

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

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JEREMY HODGE,
by his conservator ERIKA ELSON,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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* No. 9-453V
*
* Special Master Christian J. Moran
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* Filed: May 24, 2023
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* Obsessive-compulsive disorder;
* (“OCD”); hepatitis B vaccine;
* Lyme disease; neuroborreliosis;
* demyelination; significant
* aggravation; remand
*

Renee J. Gentry, Vaccine Injury Clinic, George Washington Univ. Law School,
Washington, DC, for Petitioner;
Bridget Corridon, United States Dep’t of Justice, Washington, DC, for Respondent.

PUBLISHED DECISION ON REMAND DENYING ENTITLEMENT¹

A September 12, 2022 decision found the petitioner, Erika Elson, was not entitled to compensation because she did not establish the version of events underlying the theory of the case espoused by her expert. A March 7, 2023 opinion ruled this factual finding was arbitrary and capricious, found that the

¹ Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims’ website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted in the website.

chronology of events aligned with Ms. Elson's theory of the case, and remanded the matter. The entire record has been reviewed again. Ms. Elson is not entitled to compensation.²

The primary flaw with Ms. Elson's case is that she has not met her burden of establishing that the hepatitis B vaccine can cause (or aggravate) a demyelinating condition. This issue exists independently of the facts and circumstances of what happened to Ms. Elson's son, Jeremy Hodge. A second problem with Ms. Elson's case is that she has not met her burden of establishing that Mr. Hodge experienced a series of neurologic problems sufficiently close in time to the vaccination such that an inference of aggravation is appropriate.

I. Introduction

The petitioner's claim is complex: Erika Elson alleges that (1) her son, Jeremy Hodge, developed Lyme³ disease in 2003; (2) the untreated bacterial infection progressed to a central nervous system disorder known as neuroborreliosis; (3) the Lyme disease / neuroborreliosis in turn caused him to develop obsessive-compulsive disorder ("OCD"); (4) then, the 2006 hepatitis B vaccine(s) significantly aggravated his condition.

The decision begins with an overview of the case, including information about this case's lengthy procedural history as well as a summary of the parties' positions in Section II. Next, the experts' qualifications and demeanor are assessed in Section III. The experts help to understand the evidence that has been presented. The recitation of evidence regarding Mr. Hodge's health, which is section IV, spans more than 40 pages to demonstrate that the entire record has been reviewed. An exposition on the basic standards for adjudication is found in section V.

In the analysis section, section VI, each of the Loving factors are considered separately. The factor that determines the outcome of the case is Loving prong 4, which corresponds to section VI.D. Although unnecessary to the decision, the possibility of alternative causes is considered in section VI.G.

² Some portions of the present decision repeat portions of the September 12, 2022 decision because each decision stands on its own. Cottingham v. Sec'y of Health & Hum. Servs., 971 F.3d 1337, 1345 n.2 (Fed. Cir. 2020).

³ Sometimes, the quoted portions from the medical records and transcripts originally have a lower-case "l" for Lyme disease. This decision capitalizes the "L" for Lyme disease to reflect the accuracy of the spelling.

II. Case Overview

A. Procedural History

The duration of this case is unusual, and the recitation of events during its pendency is, accordingly, lengthy as well. For approximately six years, the parties focused on determining whether the case could proceed because the statute of limitations appeared to bar the claim. Part of this process, which is described in section II.A.1 below, involved the gathering of medical records. Eventually, the undersigned found that the doctrine of equitable tolling allowed the case to proceed.

The next stage concerned the development of opinions as to whether the 2006 vaccinations caused Mr. Hodge's OCD to worsen. As discussed in section II.A.2 below, this stage ended when an entitlement hearing was cancelled to allow Ms. Elson to obtain additional records about Mr. Hodge's health in 2005 and 2006.

Section II.A.3 below recounts some of the efforts to obtain this information. Ideally, all records about Mr. Hodge's health and well-being should have been gathered from schools, doctors, and counselors much closer to when the petition was filed in 2009, not a decade later. After these efforts ended and the experts reviewed the material, the case proceeded to an entitlement hearing on June 14-15, 2021. The parties then filed briefs.

A decision denying entitlement was issued on September 12, 2022. First Entitlement Decision, 2022 WL 4954672 (Fed. Cl. Spec. Mstr. Sept. 12, 2022). Ms. Elson's claim was not persuasive because her expert assumed a set of facts that the evidence did not persuasively establish. The September 12, 2022 decision did not analyze whether the hepatitis B vaccine caused any adverse reaction in Mr. Hodge.

Ms. Elson challenged the result by filing a motion for review. The Court granted the motion for review because the Court found that there was preponderant evidence, showing the sequence of events that were the foundation for Ms. Elson's expert's opinion. The Court remanded for consideration of additional issues, including whether the hepatitis B vaccine harmed Mr. Hodge.

1. Petition through December 1, 2015 Ruling Finding Equitable Tolling⁴

Represented by Mr. Clifford Shoemaker, the petitioner filed the petition on July 15, 2009, alleging that Mr. Hodge suffered “various symptoms and injuries” after receiving hepatitis A and hepatitis B vaccines in March and April of 2006. Pet. ¶ 5-6, 8. In July 2009, the petitioner was identified as Jeremy Hodge, although whether Mr. Hodge engaged Mr. Shoemaker and whether he possessed the capacity to retain an attorney appeared unclear.

Mr. Shoemaker stated that Mr. Hodge’s mother (Ms. Elson) contacted Mr. Shoemaker less than 48 hours before Mr. Shoemaker filed the petition. Mr. Shoemaker was filing the petition as quickly as possible “to stop the running of the statute of limitations.” Pet. ¶ 11. Mr. Shoemaker further explained that he possessed only two medical records: the vaccination record and the results of a May 19, 2009 MRI.⁵ Id. Mr. Shoemaker filed those documents as exhibits 1 and 2 on November 3, 2009.

In the absence of other medical records, Mr. Shoemaker stated that Mr. Hodge “experienced various symptoms that will be described in subsequently filed affidavits from the Petitioner, his mother and perhaps other witnesses. Presumably, many of these symptoms will also be found in medical records.” Pet. ¶ 6.

On behalf of petitioner, Mr. Shoemaker sought and received authorization to serve subpoenas to gather medical records. See Pet’r’s Mot., filed July 15, 2009; Order Granting Mot., issued Aug. 31, 2009. It is not readily apparent whether Mr. Shoemaker served subpoenas on Valley Care, the institution where Mr. Hodge was allegedly diagnosed with OCD, or Dr. John Nasse, a doctor who provided mental health services to Mr. Hodge. See Resp’t’s Posthear’g Br. at 32 n.20.

The petition acknowledged a potential statute of limitations problem. Pet. ¶ 7. In the initial status conference on September 3, 2009, the Secretary raised the statute of limitations problem and consistently reminded petitioner about this

⁴ The December 21, 2015 ruling regarding equitable tolling sets out the procedural history relevant to the statute of limitations and equitable tolling issues in more detail. Ruling Finding Equitable Tolling, 2015 WL 9685916 (Fed. Cl. Spec. Mstr. Dec. 21, 2015).

⁵ Although the record states the “D/T” (likely Date of Treatment) was May 18, 2009, the date of study is listed as May 19, 2009. The parties use the May 19, 2009 date. To avoid confusion, the undersigned will refer to this MRI as occurring on May 19, 2009. See exhibit 2 and exhibit 7.2 at 210-211.

problem. Nevertheless, Mr. Shoemaker pressed forward on behalf of Mr. Hodge / Ms. Elson. Between November 2009 and January 2012, the petitioner filed medical records (exhibits 1-8, 10-12) and an affidavit from his mother (exhibit 9) in support of the claims, which are summarized below. Mr. Hodge did not submit an affidavit from himself.

After Mr. Hodge appeared to have filed most of the relevant medical records, the Secretary filed a Rule 4 report and motion to dismiss the petition on April 30, 2012. The Secretary identified some problems with the medical records that remain unresolved throughout the case. For example:

- The psychologist or psychiatrist who prescribed Zoloft in March 2005 was not identified. Resp't's Rep. at 2, citing exhibit 3 at 4.
- Dr. Rodriguez's handwritten notes from March 17, 2006 were not entirely legible. Resp't's Rep. at 2 n.2, citing exhibit 5 at 2.
- Ms. Elson called the Noble Community clinic on June 8, 2006 to complain about a neurologist who evaluated Mr. Hodge and was unfamiliar with using Zoloft to treat OCD, but the name of the neurologist and the date of evaluation were not provided. Resp't's Rep. at 4, citing exhibit 5 at 4.
- The psychologist or psychiatrist whom Mr. Hodge was seeing in April 2006 was not identified. Resp't's Rep. at 3, citing exhibit 5 at 3.
- Any VAERS report that Dr. Rodriguez may have submitted in June 2006 was not provided, if one was filed. Resp't's Rep. at 4 n.5, citing exhibit 5 at 4.⁶
- The person who prescribed Inositol that Mr. Hodge was taking in August 2006 was not identified and the reason for the prescription was not listed. Resp't's Rep. at 5, citing exhibit 4 at 15.

The Secretary additionally explained that this list related to the timeliness of filing the petition. The Secretary stated:

The parties have discussed previously the incompleteness of petitioner's medical records. However, given the potential that this claim is untimely, and the possibility that petitioner may not be entitled to attorneys' fees and costs, respondent has attempted to limit any requests for additional records to those needed to determine whether

⁶ In an affidavit filed in 2021, Ms. Elson stated that she never filed a VAERS report. Exhibit 86 at 25.

petitioner's claim is timely. Respondent reserves the right, however, to request that petitioner provide complete records from all care providers for the relevant time periods both before and after his March and April, 2006 vaccinations.

Resp't's Rep. at 18 n.14.

Beyond identifying these deficiencies among the records Mr. Hodge had filed, the Secretary raised two arguments against compensation. First, the Secretary maintained that the petition was filed beyond the time permitted by the statute of limitations. Second and briefly, the Secretary contended that Mr. Hodge had not submitted evidence to show a vaccination caused any injury, and thus the Althen factors had not been satisfied. Id. at 17-20.

At the undersigned's direction, the Secretary formally requested medical records. Resp't's Status Rep., filed May 21, 2012. In response, Mr. Shoemaker stated that counsel was working with Mr. Hodge's mother, who would be sending counsel medical records and contact information. Pet'r's Status Rep., filed July 20, 2012.⁷ Months later, no additional records had been filed. Mr. Shoemaker represented that he had not been able to speak with Ms. Elson because she was caring for Mr. Hodge. Mr. Shoemaker represented that he would send requests for records later that week. Pet'r's Status Rep., filed Oct. 25, 2012.⁸

Pursuant to an order, issued on October 26, 2012, Mr. Hodge filed medical records on January 4, 2013. Exhibits 13-14. Mr. Shoemaker discussed the efforts to obtain more records, of which the most important concerned the diagnosis and treatment for Mr. Hodge's OCD. For this problem, Mr. Shoemaker seemed to be relying upon Ms. Elson's work:

Counsel has spoken to the Petitioner's mother and she told Counsel that she was unsure of the name of the provider. She told Counsel that she drove by the building that the provider was at and they are no longer there. She said she

⁷ Mr. Shoemaker's associate, Sabrina Knickelbein, signed these status reports on behalf of Mr. Shoemaker. See Rule 83.1(c)(2) of the Rules of the Court of Federal Claims (authorizing one member of the bar to sign for counsel of record).

⁸ Medical records produced later showed that Mr. Hodge was in counseling with Dr. Dasher around this time. See exhibit 14.2 at 106-07.

would place a call into the County to see if the records exist anymore.

Pet'r's Status Rep., filed Jan. 31, 2013.

It appeared that despite some outstanding requests for records, Mr. Hodge may have produced medical records sufficient for him to respond to the Secretary's pending motion to dismiss due to untimeliness. The undersigned directed Mr. Hodge to obtain a report from an expert addressing three questions. These questions were: (1) what is a proper diagnosis for Mr. Hodge? (2) when did Mr. Hodge begin to suffer from that disease? and (3) whether any additional treatment and/or testing is appropriate for Mr. Hodge? Order, issued April 24, 2013.⁹

Mr. Shoemaker filed a status report regarding outstanding medical records requests on May 6, 2013. Counsel reported that he spoke to Ms. Elson, reviewed the file, and she indicated that all of the records for Dr. Rodriguez had been filed, thus they would no longer pursue that request. Counsel also continued to seek records from Greg Nelson, a dermatologist.

On August 23, 2013, Mr. Hodge filed an expert report from Dr. Tornatore. Exhibit 18. Dr. Tornatore opined that "the diagnosis of neuroborreliosis would not be unreasonable." Id. at 2. Furthermore, with the information available at that time, Dr. Tornatore opined that the medical records showed that the neuroborreliosis began in 2005. Id. Dr. Tornatore also stated that some of Mr. Hodge's reported symptoms (dizziness and eye movement disturbances on June 2, 2006), evidenced a worsening of his "underlying autoimmune demyelinating disorder." Id.

Although Dr. Tornatore's report filled some gaps in Mr. Hodge's evidence, Mr. Hodge had not responded to the legal arguments in the Secretary's motion to dismiss. The parties developed their legal arguments in briefs. See Pet'r's Mem., filed Jan. 30, 2014; Resp't's Resp., filed May 9, 2014; Pet'r's Sur-Reply, filed Oct. 1, 2014. With Mr. Hodge's Sur-Reply, he submitted an affidavit from Ms. Elson. Exhibit 19.

The undersigned granted the Secretary's motion to dismiss based upon two rulings. First, the undersigned determined that Mr. Hodge filed his petition after the statute of limitations elapsed. Second, the undersigned found that Mr. Hodge did not establish his mental illness justified equitable tolling. Decision on Statute

⁹ During the status conferences held to discuss the collection of medical records, the Secretary continued to question the reasonable basis for this claim. See orders dated June 27, 2013; April 24, 2013.

of Limitations, 2015 WL 1779274 (Fed. Cl. Spec. Mstr. Mar. 23, 2015). This decision, however, did not lead to a judgment. Mr. Hodge filed a motion for review. The Court vacated the aspect of the March 23, 2015 decision concerning equitable tolling and remanded for additional consideration. First Opinion and Order, 123 Fed. Cl. 206 (2015).

On remand, the parties filed additional evidence regarding Mr. Hodge's mental capacity. See, e.g., exhibit 20 (records from Dr. Glenn Mathisen and Dr. Wendy Clough, contemplating potential problems Mr. Hodge might have been experiencing, including Lyme disease and other issues); exhibit 21 (affidavit from Ms. Elson); exhibit 22 (report of Robert Dasher, a psychiatrist who treated Mr. Hodge); exhibit A (report of Elizabeth LaRusso, a psychiatrist the Secretary retained); exhibit C (report of John Dunn, a neuropsychologist the Secretary retained). Mr. Hodge filed another affidavit from his mother, who challenged some factual assertions made by Dr. LaRusso and Dr. Dunn. Exhibit 26.

The undersigned found that Mr. Hodge qualified for equitable tolling. Ruling Finding Equitable Tolling, 2015 WL 9685916. The undersigned held, as a matter of law, that the Vaccine Act authorized equitable tolling for mental illnesses.¹⁰ The undersigned also held that to be entitled to equitable tolling, a claimant must establish that he is "incapable of handling his own affairs." Id. at *8, quoting Barrett v. Principi, 363 F.3d 1316, 1321 (Fed. Cir. 2004). Based upon the evidence, the undersigned found that Mr. Hodge's mental illness deprived him of the ability to handle his own affairs, justifying equitable tolling. Id. at *24. Finally, the undersigned suggested that the finding that Mr. Hodge could not handle his own affairs implied that Mr. Hodge should not be the petitioner in this case. Id.

2. Development of Expert Opinions and Initial Scheduling of Entitlement Hearing

The December 21, 2015 ruling allowed the case to proceed. The first task was to resolve who should be the petitioner. Mr. Shoemaker stated that Ms. Elson intended to become the conservator for Mr. Hodge through the California Probate Court. Pet'r's Status Rep., filed Jan. 20, 2016. On October 4, 2016, Mr.

¹⁰ The Federal Circuit later agreed with this holding. K.G. v. Sec'y of Health & Hum. Servs., 951 F.3d 1374, 1381 (Fed. Cir. 2020).

Shoemaker filed an order appointing Ms. Elson conservator. Exhibit 28. Based upon this order, Mr. Shoemaker sought to amend the caption.¹¹

Once the identity of the petitioner was resolved, the parties proceeded to develop evidence related to causation in earnest. An October 24, 2016 order structured the next steps. The Secretary suggested obtaining *updated* medical records and Mr. Shoemaker was agreeable. In retrospect, Mr. Shoemaker should have done more to obtain records, such as school records and medical records, created before 2006 and around the time of the vaccinations in 2006. However, it appears that by 2016, all participants (including the undersigned) had failed to appreciate that the petitioner should gather more information about Mr. Hodge's health before and shortly after the vaccinations. In any event, Mr. Shoemaker wanted to obtain a report from Dr. Tornatore in which Dr. Tornatore could explain how the vaccinations significantly aggravated Mr. Hodge's pre-existing OCD. To further this process, the undersigned proposed a set of instructions for preparation of expert reports. Order, issued Oct. 24, 2016. These instructions directed the experts to present opinions regarding the expected course of OCD. Final Instructions, issued Nov. 22, 2016, ¶ 4.b.

The petitioner, now Ms. Elson, filed Dr. Tornatore's report on January 23, 2017. Exhibit 29. In presenting this report, Dr. Tornatore did not address the expected course of OCD. See id. The next day, Ms. Elson filed two more medical records. Exhibits 31-32. Ms. Elson added another set of medical records on February 17, 2017. Exhibit 33.

Ms. Elson filed an amended petition on March 6, 2017. The amended petition was short, barely more than one page. Based on Dr. Tornatore's report, the amended petition alleged that the 2006 vaccinations significantly aggravated Mr. Hodge's neuroborreliosis. Am. Pet., filed Mar. 6, 2017, ¶ 6.¹²

A status conference was held on February 9, 2017 to discuss Dr. Tornatore's expert report, filed on January 23, 2017. During this conference, the parties indicated that records from a psychiatrist or psychologist who treated Mr. Hodge might be necessary. Accordingly, Ms. Elson was directed to file a status report regarding records from a psychiatrist or psychologist. Order, issued Feb. 13, 2017.

¹¹ The caption was officially modified on November 9, 2016.

¹² Around this time, the undersigned awarded attorneys' fees and costs on an interim basis. First Interim Fees Decision, 2017 WL 1315716 (Fed. Cl. Spec. Mstr. Mar. 9, 2017). The undersigned issued a second decision awarding interim attorneys' fees and costs on May 3, 2017. Second Interim Fees Decision, 2017 WL 2333626 (Fed. Cl. Spec. Mstr. May 3, 2017).

Ms. Elson, in turn, represented that the “Petitioner has filed all of his psychiatrist and psychologist records.” Pet’r’s Status Rep., filed Mar. 15, 2017.

In retrospect, again, the undersigned should not have accepted this two-sentence status report. The undersigned should have demanded that Ms. Elson and/or Mr. Shoemaker submit an affidavit describing efforts to obtain records from a psychiatrist and/or psychologist. See Vaccine Rule 2(c)(2)(B)(1); Guidelines for Practice Under the Nat’l Vaccine Injury Compensation Program, Section II, Chapter 3, paragraph B.13. However, the undersigned accepted the representation of Mr. Shoemaker.

On August 4, 2017, the Secretary responded to Dr. Tornatore’s report by submitting a report from Arun Venkatesan. Exhibit E. Dr. Venkatesan opined that the course of OCD waxes and wanes. Thus, any worsening of Mr. Hodge’s OCD after the 2006 vaccinations reflects a natural course of OCD, which he opined was not caused by the vaccinations.

This case was then scheduled for a one-day hearing on November 5, 2018. Order, issued Sept. 21, 2017. This order encouraged Ms. Elson to attend the hearing.

On December 18, 2017, Ms. Elson filed a supplemental report from Dr. Tornatore, which was approximately two pages. Exhibit 34. Dr. Tornatore did not address topics listed in the August 9, 2017 order, such as the expected course of OCD. Accordingly, Ms. Elson was barred from introducing testimony from Dr. Tornatore about these topics in the forthcoming hearing. Order, issued Dec. 22, 2017.

In anticipation of the November 5, 2018 hearing, the undersigned directed the parties to file briefs and other material, such as updated medical records. Order, issued March 23, 2018. This order again encouraged Ms. Elson’s participation in the hearing. Id. at 10 n.6. The March 23, 2018 order referenced the December 22, 2017 order limiting Dr. Tornatore’s testimony.

After being reminded about the December 22, 2017 order, Ms. Elson sought reconsideration of the order restricting Dr. Tornatore’s testimony to the topics on which he had opined. Pet’r’s Mot., filed Apr. 30, 2018. With her motion, Ms. Elson submitted another report from Dr. Tornatore. Exhibit 35. The Secretary stated that he would not be prejudiced by consideration of this report. Resp’t’s Resp., filed June 13, 2018. In the absence of an objection from the Secretary, Dr. Tornatore’s April 30, 2018 report was accepted. Order, issued June 19, 2018.

After receiving enlargements of time, Ms. Elson filed her brief on June 28, 2018. Before and in conjunction with this submission, Ms. Elson also filed medical records and medical articles. The Secretary filed his brief on August 15, 2018.

Based upon the parties' arguments, a lengthy and substantive status conference was held on September 7, 2018. The undersigned advised that the hearing should be extended from one day to two days. Based upon the availability of the attorneys, Dr. Tornatore, and Dr. Venkatesan, the hearing was rescheduled for January 10-11, 2019. Order, issued Sep. 17, 2018.

In the September 7, 2018 status conference, the undersigned also suggested that Ms. Elson should testify. Mr. Shoemaker represented that rather than testifying orally at a hearing, Ms. Elson could present a comprehensive affidavit. In addition, the undersigned ordered Ms. Elson to file a series of documents, including Mr. Hodge's school records, a list of payments from any insurance company, and records from Dr. Nasse. Order, issued Sept. 7, 2018. To ensure that Ms. Elson's affidavit was comprehensive, the undersigned propounded a series of questions for her to answer. Order, issued Sept. 13, 2018; see also 42 U.S.C. § 300aa-12(d)(3)(B)(iii) (authorizing special master to require the testimony of any person).

Ms. Elson began to submit additional documents. The collection of school records, unfortunately, contained relatively little useful information because the school systems did not retain all records. See exhibits 58, 60-61. Attempts to obtain medical records were also sometimes unsuccessful. See exhibits 62, 64. One notable example of missing records was records from the doctor who provided mental counseling to Mr. Hodge, Dr. Nasse. Exhibit 70.

Ms. Elson requested additional time to file her comprehensive affidavit. See Pet'r's Mot., filed Oct. 9, 2018; Pet'r's Mot., filed Oct. 22, 2018; Pet'r's Mot., filed Nov. 6, 2018. Ms. Elson finally submitted her comprehensive affidavit on November 26, 2018. Exhibit 71. This affidavit generally did not answer many questions put forth in the September 13, 2018 order.

Although the undersigned had anticipated that Dr. Tornatore and Dr. Venkatesan would review any additional documents and present supplemental reports before the hearing starting on January 10, 2019 (see order, issued Oct. 24, 2018), this task was not possible. Ms. Elson had not collected many documents. For example, Ms. Elson had not obtained documents from the insurance company showing a list of payments to doctors who had treated Mr. Hodge. See Pet'r's Mot. for Subpoena, filed Oct. 26, 2018. This list could have identified doctors

whom Ms. Elson did not recall. Without a complete set of documents describing Mr. Hodge's condition before and around the time of his vaccinations in 2006, the undersigned reluctantly cancelled the hearing. Order, issued Nov. 28, 2018.

3. Attempts to Gather More Factual Materials Through Entitlement Hearing

After the hearing was cancelled, Mr. Shoemaker intensified efforts to obtain medical records. Mr. Shoemaker submitted motions to authorize him to subpoena various institutions that possessed either medical records or school records for Mr. Hodge. This process garnered little useful information. See, e.g., exhibit 72.

Efforts to obtain information from the insurance company that paid for Mr. Hodge's medical care were especially protracted. Repeatedly, Mr. Shoemaker seemed to be close to receiving useful information only to learn later that his request was misdirected. See, e.g., Pet'r's Status Rep., filed July 12, 2019.

Mr. Shoemaker was replaced as Ms. Elson's counsel of record by Renee Gentry on October 30, 2019. Ms. Gentry continued to represent Ms. Elson and continued the process of attempting to gather information from an insurance company about payments to doctors. See Pet'r's Status Rep., filed Jan. 6, 2020.

The persistence of Mr. Shoemaker and Ms. Gentry eventually led to a list of medical providers. Ms. Gentry filed a list on February 27, 2020 as exhibit 80. From this list, Ms. Gentry intended to seek additional records. However, by this time, the coronavirus pandemic had caused delays in obtaining records from medical facilities. Eventually, some potential sources of information responded that they did not have information. See exhibit 82.

The parties determined that by August 2020, Ms. Gentry and Ms. Elson had exhausted all possible sources of written information about Mr. Hodge. Thus, the parties were directed to provide the material that Mr. Shoemaker and Ms. Gentry had discovered to the experts the parties had retained. Order, issued Aug. 25, 2020.

The recently produced material did not affect the opinions of either Dr. Tornatore or Dr. Venkatesan. Dr. Tornatore took the opportunity to restate his opinions and to reorganize his presentation in a comprehensive report. Exhibit 83. Dr. Venkatesan wrote four sentences. Exhibit I.

The undersigned, again, attempted to mark the case down for a hearing. As a preliminary step, Ms. Elson was to determine whether she would testify at a hearing because her participation would influence the duration of the hearing. Order, issued Nov. 12, 2020. Ms. Elson stated that she did not want to testify live.

Instead, she wanted to file an updated affidavit. Pet'r's Status Rep., filed Dec. 14, 2020.

Ms. Elson's request to submit an affidavit was granted. However, the undersigned noted that Ms. Elson had not responded to the questions posed to her in the September 13, 2018 order. Answering those questions could be important. In addition, information about Mr. Hodge's functioning in the years since Ms. Elson's previous affidavit would not likely affect whether the vaccinations in 2006 harmed Mr. Hodge. Order, issued Dec. 23, 2020.

The December 23, 2020 order also set out deadlines for scheduling a two-day hearing as well as the submission of briefs before the hearing. A mutually convenient time for a hearing was found to be June 14-15, 2021. Thus, a hearing was ordered for those dates. Order, issued Jan. 22, 2021.

Ms. Elson filed her affidavit on February 3, 2021. Exhibit 86. Ms. Elson appeared to make a good-faith effort to answer all the questions set forth in the September 13, 2018 order, although she did not address all questions entirely. Ms. Elson's affidavit was considered, and its contents are set forth in the recitation of evidence below. Ms. Elson submitted her brief on February 24, 2021.

Following the submission of Ms. Elson's affidavit and her brief, the undersigned issued a series of orders to clarify the record. For example, Ms. Gentry drafted and filed two affidavits regarding how medical records were collected. Exhibits 87-88. The Secretary declined to explore settlement. Resp't's Status Rep., filed March 24, 2021. The same day, the Secretary filed his brief, arguing Ms. Elson was not entitled to compensation. Ms. Elson addressed some of those arguments. Pet'r's Prehear'g Reply Mem., filed Apr. 26, 2021.

In his brief, the Secretary requested that Ms. Elson testified orally at the upcoming hearing. Resp't's Prehear'g Mem. at 43, filed Mar. 24, 2021. In response, Ms. Elson stated that she "will make herself available to testify should the Court require it[.]" although Ms. Elson questioned whether her testimony in 2021 could add to what she had stated in her affidavits and what is contained in the medical records. Pet'r's Status Rep., filed Apr. 1, 2021. Based upon the lack of objection from Ms. Elson as well as the undersigned's previously expressed interest in obtaining testimony from Ms. Elson, the undersigned scheduled time for Ms. Elson to testify. Order, issued April 15, 2021. See La Londe v. Sec'y of Health & Hum. Servs., 110 Fed. Cl. 184, 204 (2013) (indicating when a special master is concerned about the sufficiency of evidence presented via affidavit, the special master should compel the attendance of the affiant via a subpoena), aff'd, 746 F.3d 1334 (Fed. Cir. 2014).

On June 14 and 15, 2021, a hearing was held. Ms. Elson testified at the hearing, as did Dr. Tornatore and Dr. Venkatesan. On June 17, 2021, the parties were ordered to file post-hearing briefs.

Ms. Elson filed her post-hearing brief on September 20, 2021. The Secretary filed his post-hearing brief on December 3, 2021. On February 1, 2022, Ms. Elson submitted a reply brief.

On February 10, 2022, to address remaining issues and clarify the parties' positions on several matters, the undersigned scheduled an oral argument and provided a list of questions for the parties to prepare to address. The oral argument was held on March 17, 2022. At this point, it was evident the parties had exhaustively stated their positions and that no more evidence would be uncovered to fill in the gaps.

4. September 12, 2022 Decision Denying Entitlement

Ms. Elson was found not entitled to compensation in the September 12, 2022 Decision. The reason was that Dr. Tornatore assumed that Mr. Hodge developed Lyme disease and its associated neuroborreliosis before Mr. Hodge developed OCD and that Ms. Elson had not established this sequence of events with persuasive evidence. Because the facts, as found in the September 12, 2022 Decision, did not match Dr. Tornatore's assumptions, further analysis of his opinion that the hepatitis B vaccination(s) significantly aggravated Mr. Hodge's OCD was not necessary. First Entitlement Decision, 2022 WL 4954672, mot. for rev. granted, 164 Fed. Cl. 633 (2023).

On October 12, 2022, Ms. Elson challenged the denial by filing a motion for review. The Secretary, on the other hand, supported the result of the September 12, 2022 Decision. Resp't's Resp., filed Nov. 10, 2022.

5. March 7, 2023 Opinion and Order

The Court of Federal Claims found that the failure to discuss various medical records made the September 12, 2022 Decision arbitrary and capricious. Further, pursuant to 42 U.S.C. § 300aa-12(e)(2)(B), the Court found the following facts: "(1) Mr. Hodge exhibited symptoms of OCD by September 28, 2004, and (2) Mr. Hodge's tick exposures and subsequent Lyme disease predated his OCD symptoms." Second Opinion and Order, 164 Fed. Cl. 633, 649 (2023). The Court's findings meant that Dr. Tornatore's opinion could not be rejected on the ground that this opinion was based upon an erroneous set of facts. "Consequently, petitioner's entitlement to compensation must be resolved anew." Id.

For this purpose, the Court remanded “the case to the special master with instructions to reevaluate petitioner’s entitlement to compensation.” *Id.* Because the September 12, 2022 Decision did not discuss the Loving prongs, the Second Opinion and Order did not explicitly discuss whether the hepatitis B vaccination can cause (or aggravate) demyelination.

6. Proceedings on Remand

As part of its Order, the Court stated that: “On remand, the special master shall not require the submission of any additional evidence or legal argument unless this prohibition would result in erroneous findings of fact or conclusions of law...” *Id.* Accordingly, the undersigned has not requested any additional evidence or legal argument. The undersigned convened one status conference on March 21, 2023 during which the Secretary disclaimed any interest in resolving the case informally.

As part of the remand, the undersigned has again reviewed the record entirely. *See* 42 U.S.C. § 300aa–13. This Decision necessarily focuses upon the evidence that the parties have emphasized in their briefs.

B. A Brief Summary of the Parties’ Positions

This section contains a condensed recitation of the parties’ positions, highlighting the major points of contention between the parties. The position statements below are derived from the post-hearing briefs. A more comprehensive explanation of the evidence and arguments follow in subsequent sections.

1. Petitioner’s Positions

According to Ms. Elson, her attorneys, and Dr. Tornatore, the facts of this case are as follows. Mr. Hodge was healthy and happy prior to 2003. *See, e.g.,* Pet’r’s Posthear’g Br., at 4. Mr. Hodge was 15-16 years old during that year. At some point in 2003, during a camping trip, Mr. Hodge was bitten by a tick carrying *Borrelia Burgdorferi*, the pathogenic spirochete (spiral-shaped bacteria) which can cause Lyme disease and neuroborreliosis (a *Borrelia* infection of the central nervous system with neurologic manifestations).¹³ *Id.* at 4, 8, 48. As such, Mr. Hodge developed Lyme disease. Subsequently, the Lyme disease progressed to neuroborreliosis and caused Mr. Hodge to develop OCD. *Id.* at 4-5. Despite the

¹³ In the parties’ briefs and in some medical records, the phrase “neurolyme” is occasionally used. It seems this term is being used interchangeably with “neuroborreliosis.”

Lyme disease and Lyme-induced OCD, Mr. Hodge lived a mostly normal life. Id. at 5. Difficulties with OCD were manageable.

On March 17, 2006, Mr. Hodge received the hepatitis A and B vaccines. Symptoms suggestive of an adverse reaction followed, including fatigue, stabbing pains, and uncontrollable eye movements. Id. at 6. Mr. Hodge returned to the same clinic to receive a hepatitis B booster vaccine on April 25, 2006. After the second shot, “[a]ll hell broke loose.” Id. (quoting Ms. Elson, Tr. at 150). A host of problems followed, indicating his psychiatric symptoms had been significantly aggravated. See, e.g., Pet’r’s Posthear’g Br. at 6-7, 17, 23, 26. He went to emergency rooms multiple times in 2006, indicating a radical change in his health. Id. at 9-11. He continued to seek treatment, though he had fewer encounters with medical professionals in 2007 and 2008. Id. at 11-12.

In 2009, Mr. Hodge received MRIs of his brain that indicated the presence of a demyelinating condition. Id. at 12. Bloodwork performed in 2009 also indicated he had Lyme disease. Id. at 13. Mr. Hodge had many hospital visits in 2009 that elucidated underlying health concerns. Id. at 13-15. Mr. Hodge and his mother continued to see doctors between 2010 and 2016 seeking clarification and treatment. Id. at 15-16. Ms. Elson became Mr. Hodge’s conservator in 2016. Id. at 18.

In sum, Mr. Hodge developed Lyme-induced OCD in 2003, which was manageable until the 2006 hepatitis B vaccinations significantly aggravated his underlying condition. Id. at 17-18.

2. Respondent’s Responses

The Secretary disputes many aspects of Ms. Elson’s version of events, as well as the sufficiency and reliability of the evidence proffered. The Secretary argues petitioner has not shown the subject vaccinations can or did cause a significant aggravation of neuroborreliosis. Resp’t’s Posthear’g Br. at 5-6. This aspect of the Secretary’s position concerns the medical theories that correspond to the Althen prongs. Id. at 53-66.¹⁴

In the Secretary’s view, Mr. Hodge’s condition after the vaccines is consistent with the natural course of OCD. Id. at 6. But, the Secretary also argues

¹⁴ The Secretary contested the facts regarding the onset of Mr. Hodge’s OCD and Lyme disease. However, in light of the Court’s March 7, 2023 Opinion and Order, those challenges are no longer viable.

the burden of proof has not shifted to him because the petitioner has not presented a *prima facie* case. Id. at 66-67.

In sum, the Secretary disputes nearly all aspects of petitioner's position. The factual evidence is insufficient and unreliable; the medical theories are not well supported; and in the alternative, the series of events is better explained by the natural course of Mr. Hodge's pre-existing condition.

III. Expert Qualifications and Demeanor

This section covers four topics: (A) the qualifications of Dr. Tornatore, (B) the qualifications of Dr. Venkatesan, (C) a comparison of those qualifications, and (D) the experts' demeanor while testifying.

A. Dr. Tornatore's Qualifications

Dr. Tornatore earned his undergraduate degree in neurobiology at Cornell University. Exhibit 84 at 2 (curriculum vitae). He obtained his medical degree at Georgetown University School of Medicine and completed his residency in neurology at Georgetown University Hospital. Id.; Tr. at 9. After his residency, he was a senior staff fellow at the National Institutes of Health, examining neuroimmunology and neuroinfectious disorders. Id. He is board certified in neurology. Exhibit 84 at 1.

Currently, Dr. Tornatore is the professor and chairman of the Department of Neurology at Georgetown University Medical Center. Id. at 3; Tr. at 9. He serves as the chief and chairman of the Department of Neurology for MedStar Georgetown Hospital. Id. He is also the regional director for neurology for the whole Medstar system, so he oversees ten hospitals as well as their clinical, research and educational missions. Tr. at 9-10. In his clinical role, he treats patients with neuroimmunologic and neuroinfectious disorders, which frequently overlap. Tr. at 10.

Dr. Tornatore treats "well over 100 patients with Lyme disease," some of whom he has been treating for almost three decades since they were transferred to his care after Dr. Andy Pachner, "one of the mavens of neurolyme," left the practice. Id. at 11-12. With Dr. Pachner and others, Dr. Tornatore wrote one article on Lyme disease. Id. at 273. This article was published in 1991. Exhibit 84 at 14. Dr. Tornatore makes an original (de novo) diagnosis of Lyme disease approximately once or twice per year. Tr. at 276.

In addition to treating patients with Lyme disease, Dr. Tornatore treats a large number of patients that have psychiatric conditions that are due to the

inflammatory diseases of the nervous system, including depression, obsessive-compulsive disorder, and anxiety. Id. at 12-13. Dr. Tornatore expressed confidence in his competence in understanding Mr. Hodge's case since he trained with Dr. Jonathan Pincus, "who was kind of the father of behavioral neurology." Id. at 13. A team of people with whom Dr. Tornatore works tests patients to determine whether they suffer from OCD. Id. at 275. Dr. Tornatore estimated that because his group has more than three thousand patients with multiple sclerosis and more than ten percent of them have OCD, "over 200 of our patients have OCD." Id. at 456.

Dr. Tornatore was offered and accepted as an expert in the field of neurology. Tr. at 13-14.

B. Dr. Venkatesan's Qualifications

Dr. Venkatesan attended University of California Berkeley for his undergraduate study in bioengineering. Exhibit L at 1 (curriculum vitae). He subsequently attended UCLA for his M.D. and Ph.D. degrees. Id. His Ph.D. degree was in microbiology, for the study of viral pathogenesis. Id.; Tr. at 340. At Johns Hopkins, he completed his residency in neurology as well as a fellowship in neuroimmunology and neuroinfectious diseases. Id. He has been on the faculty at Johns Hopkins in the division of neuroimmunology and neuroinfectious diseases since 2007. Id.

Dr. Venkatesan currently is an associate professor of neurology at Johns Hopkins University School of Medicine. Exhibit L at 1. He routinely lectures on clinical manifestations of nervous system Lyme disease as well as approaches to treatment and management of Lyme disease to medical students, fellows, and physicians. Tr. at 341. He has also been published on nervous system manifestations of Lyme disease. Id.; Exhibit L at 6. He is the director of the Johns Hopkins Encephalitis Center and a member of both the Multiple Sclerosis Center at Johns Hopkins and Johns Hopkins Lyme Disease Research Center. Exhibit L at 1; Tr. at 339. As the director of the Encephalitis Center, a multi-disciplinary program where neurologists work with doctors in infectious disease, neuropsychology, and pathology, Dr. Venkatesan coordinates and oversees the clinical and research programs devoted to understanding more about the pathogenesis of encephalitis and developing new strategies for diagnosis and treatment. Tr. at 340.

At the Lyme Disease Center, he treats patients with Lyme Disease "both in the acute and chronic setting in an effort to try to help these patients with an acknowledgement that [the doctors] really don't know enough yet about the

pathogenesis of the nervous system Lyme disease.” *Id.* at 341. Dr. Venkatesan treats mostly patients with Lyme disease that also have neurolyme, which include approximately 2% of patients with OCD. *Id.* at 342. Dr. Venkatesan estimated that the Lyme Disease Center includes “probably one of the largest cohorts of patients with Lyme disease in the country at this point and we’re consistently getting new patients referred to us as a result.” *Tr.* at 402. Dr. Venkatesan stated that “we” make a new diagnosis of Lyme disease at least two times per month. *Id.* Like Dr. Tornatore, Dr. Venkatesan works with a team of professionals, including psychiatrists, when a patient is suspected to have OCD. *Id.*

Dr. Venkatesan was offered and accepted as an expert in the field of neurology and immunology. *Tr.* at 346-47.

C. Comparison of Dr. Tornatore’s and Dr. Venkatesan’s Qualifications

Special masters may consider the relative expertise of testifying experts when weighing the value of their opinions. *See Depena v. Sec’y of Health & Hum. Servs.*, No. 13-675V, 2017 WL 1075101 (Fed. Cl. Spec. Mstr. Feb. 22, 2017), *mot. for rev. denied*, 133 Fed. Cl. 535, 547-48 (2017), *aff’d without op.*, 730 Fed. App’x 938 (Fed. Cir. 2018); *Copenhaver v. Sec’y of Health & Hum. Servs.*, No. 13-1002V, 2016 WL 3456436 (Fed. Cl. Spec. Mstr. May 31, 2016), *mot. for rev. denied*, 129 Fed. Cl. 176 (2016).

As discussed in more detail, the experts’ opinions cover at least three topics: (1) myelination / demyelination, (2) Lyme disease, and (3) OCD. These respective topics are covered below.

Myelination / Demyelination: Dr. Tornatore and Dr. Venkatesan are strongly qualified to discuss myelin. Both teach and see patients at centers devoted to multiple sclerosis at leading institutions --- Georgetown for Dr. Tornatore and Johns Hopkins for Dr. Venkatesan. Trying to differentiate their knowledge about myelination would be quibbling.

Lyme disease: Although Dr. Tornatore is sufficiently qualified as a neurologist to discuss Lyme disease and neuroborreliosis, Dr. Tornatore lacks the more focused work that Dr. Venkatesan has done. While Dr. Tornatore published one article on Lyme disease more than three decades ago, Dr. Venkatesan has written two articles in the last ten years. More significantly, Dr. Venkatesan works at the Johns Hopkins Lyme Disease Research Center. Exhibit L at 1; *Tr.* at 339. He is currently receiving funding from the Department of Defense to investigate Lyme disease. Exhibit L at 7. He has been an invited speaker to talk about Lyme

disease because he is considered to “have some level of expertise.” Tr. at 401. Therefore, on the topic of Lyme disease, Dr. Venkatesan has stronger credentials.

OCD: Dr. Tornatore and Dr. Venkatesan are qualified to discuss OCD because they are both neurologists. However, they both appear to lack any in-depth specialized knowledge. For example, neither Dr. Tornatore nor Dr. Venkatesan have written articles on OCD that have appeared in peer-reviewed journals. While both treat patients with OCD, it appears that the actual treatment for OCD is supervised by other professionals on Dr. Tornatore’s and Dr. Venkatesan’s teams. Under these circumstances, the undersigned declines to find either Dr. Tornatore or Dr. Venkatesan superior (or inferior) to the other on the topic of OCD.¹⁵ But see Dean v. Sec’y of Health & Hum. Servs., No. 13-808V, 2017 WL 2926605, at *8 n.7 (Fed. Cl. Spec. Mstr. June 9, 2017) (indicating a lack of expertise from experts retained by both parties on an issue tends to hurt petitioner’s case more because the petitioner bears the burden of proof).

D. The Experts’ Demeanor

Special masters may consider the demeanor of experts during their testimony as part of assessing an expert’s credibility. “Assessments as to the reliability of expert testimony often turns on credibility determinations, particularly in cases . . . where there is little supporting evidence for the expert’s opinion.” Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1325-26 (Fed. Cir. 2010) (citing cases). “Finders of fact are entitled-indeed, expected-to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.” Id. at 1326. However, special masters may not use an “unduly stringent legal test while characterizing the rejection as based on . . . the credibility of a particular witness.” Id., citing Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009).

In a handful of instances, Dr. Tornatore’s demeanor diminished his credibility and persuasiveness on certain topics. In these places, which are discussed throughout this decision, Dr. Tornatore appeared to stretch foundational information beyond reasonable bounds. Thus, on some topics, the undersigned is giving Dr. Tornatore’s testimony less weight. However, these instances were not so numerous to call into question Dr. Tornatore’s overall credibility. Throughout

¹⁵ Given that Mr. Hodge was diagnosed with OCD before the vaccinations and he has asserted that the vaccinations worsened his OCD, both parties may have benefited from retaining people who regularly treat people with OCD as a primary part of their practices.

most (but not all) of his testimony, Dr. Tornatore's demeanor did not lessen his persuasiveness.

Dr. Venkatesan's demeanor was acceptable. The undersigned's first-hand observations of Dr. Venkatesan during testimony did not suggest that Dr. Venkatesan was modifying his opinions for the purposes of litigation.

IV. Recitation of Evidence¹⁶

As discussed above, the evidence in this case is less than ideal. The peculiar circumstances compel a particular presentation; a chronological discussion is more complicating than clarifying under the conditions of this case. Much of the evidence regarding what may have happened in a given year is derived from testimony provided years later. For example, there are no records created in 2003 that illuminate the events of that year, but plenty of testimony has been generated discussing what may have happened in 2003.

If this evidence had been reliable, consistent, and developed in a timely fashion, the undersigned would have presented the evidence in a chronological order. However, under these circumstances, the evidence is recited and evaluated based upon the source from which it was derived. Contemporaneously created medical records receive a rebuttable presumption of validity. In contrast, although testamentary evidence must be considered, it does not receive the same presumption of validity. Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). Furthermore, special masters are not required to accept party assertions as facts, particularly when there is reason to doubt the veracity of a given claim. But cf. Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1383 (Fed. Cir. 2021).

During the course of litigation, Ms. Elson was involved in creating numerous affidavits. At a macro level, they tell a similar story. However, some inconsistencies are discussed in specific parts of the decision. For reference, Ms. Elson's affidavits are listed below.

Exhibit Number	Filing Date	ECF #
Exhibit 9	January 14, 2011	33
Exhibit 19	October 1, 2014	97

¹⁶ As with the procedural history, much of the recitation of evidence is taken from the September 12, 2022 First Entitlement Decision. However, various additions and corrections have been made to reflect evidence cited in the Court's March 7, 2023 Opinion and Order.

Exhibit 21	October 16, 2015	124
Exhibit 26	December 4, 2015	135
Exhibit 71	November 26, 2018	245
Exhibit 86	February 3, 2021	335

Due to these problems, the undersigned has spent additional time independently reviewing all evidence to understand Mr. Hodge's health during critical times.

The evidence below, in sections IV.A and IV.B, is divided into events before the subject vaccinations and events contemporaneous with and after the vaccinations. Within these categories, evidence gleaned from medical and school records merit their own sub-sections. Next, testamentary evidence is summarized, which at times corroborates, contradicts, and complements the medical records. The subsequent section concerns expert commentary, which necessarily relies on the facts and assertions from the preceding sections.¹⁷

A. Mr. Hodge's Health and Condition(s) Before the 2006 Vaccinations

The following section concerns Mr. Hodge's health prior to the 2006 vaccinations. Information is derived from (1) medical records; (2) school records; (3) statements and evidence regarding missing and unavailable records; (4) testimony, including affidavits and oral statements; and (5) expert commentary. Paragraph (6) restates the Court's binding findings of fact.

¹⁷ However, out of necessity, some fact-finding occurs within each section. For example, the undersigned states his interpretations of handwritten medical records that are difficult to decipher, blurring the line between reciting evidence and finding facts about the content of the evidence.

1. Medical Records

Jeremy Hodge was born on May 15, 1987. Exhibit 3.1. The medical records from Mr. Hodge's pediatrician, Dr. Lawrence Menzer, recount relatively routine illnesses associated with childhood. See exhibits 3.1 and 3.2, passim.¹⁸ Mr. Hodge received routine childhood immunizations in the late 1980s and early 1990s. Exhibits 1 and 3.1.

Though the handwritten descriptions are difficult to read, each entry is clearly stamped with a date of the visit. Mr. Hodge's mother regularly took him to Dr. Menzer's office. These include more than 10 visits in 1987, more than 10 visits in 1988, about 5 visits in 1989, about 4 visits in 1990, about 3 visits in 1991, about 5 visits in 1992, about 4 visits in 1993, and at least 1 visit each in 1994, 1995, and 1996. Exhibit 3.1, passim. Some words and phrases are legible, such as "sick," "fever," "cough," "stuffy nose," "viral syndrome," "bad cold," "tongue hurts."

It appears Dr. Menzer referred Mr. Hodge to Dr. Greg Nelson, a dermatologist, in 1996, when Mr. Hodge was 9 years old. Exhibit 3.2 at 22. A letter dated July 18, 1996 states Mr. Hodge was evaluated three days prior by Dr. Nelson. The letter states: "Jeremy is bothered by a rash on the bottom of his feet that has been present for several years. The mother feels that the use of his high topped shoes has aggravated this. In reality, this rash, although prominent is entirely asymptomatic." Id.; exhibit 15 (duplicate of Dr. Nelson's note). The dermatologist's impression was granuloma annulare, and Mr. Hodge was given an ointment for treatment.¹⁹

As explained in the introduction and elsewhere in this decision, an unfortunate issue in this case is the absence of medical records and other notes describing contemporaneous events. There are no *available* doctors' notes or other

¹⁸ Unfortunately, much of Dr. Menzer's notes are handwritten. The parties and the undersigned have struggled to decipher the content. See, e.g., Pet'r's Prehear'g Mem., filed June 28, 2018, at 1 (summarizing events between 2004 and 2006 with one sentence); Resp't's Rep., filed Apr. 30, 2012, at 2 (skipping over content in recitation of facts). Some information is readily intelligible; other content is unlikely to ever be decoded. This is one among many examples of suboptimal records.

¹⁹ The Secretary stated granuloma annulare is a chronic skin disease that manifests as a rash with reddish bumps arranged in a circle or ring, that is sometimes itchy and occasionally associated with diabetes and thyroid disease. Resp't's Rep. at 2 n.1. This assertion was not discussed by the experts subsequently retained to opine in this case.

records between July 1996 and March 2004 that document Mr. Hodge's health. See also Resp't's Posthear'g Br. at 6 n.4 (arguing Mr. Hodge was seen by other care providers during this period, despite the lack of available records). This eight-year gap makes it difficult to understand Mr. Hodge's health before the 2006 vaccinations.

After the gap, some medical records exist that elucidate Mr. Hodge's health when he was 17 years old. The handwritten notes, which are difficult to decipher, from Dr. Menzer indicate that on March 10, 2004, Mr. Hodge was evaluated for "sinus pressure x 2 mo."²⁰ Exhibit 3.1 at 3. It seems a diagnosis of nasal allergies was probably written. The subsequent note on the page suggests Mr. Hodge returned on April 19, 2004; it appears sinus pressure and nasal discharge are discussed, and amoxicillin may have been prescribed, but the rest of the note is incomprehensible. Id. The next recorded date is September 7, 2004, which seems to read: "Per mom would like Rx for Zyrtec – D, called in Rx: 0/1 tab PO 1-2 times/day #30." Id.

The next line in Dr. Menzer's notes is dated September 28, 2004. It appears to state: "Per mom was given Amox 500 mg over the weekend by Dr. on call – sinus inf. – doing better per mom. Also mom said he was put on Adderall per psych. Advised px will call back to schedule yp." Records from the Ojai Village Pharmacy suggest Dr. Nasse prescribed Risperdal on September 27, 2004, and Adderall on September 28, 2004. See exhibit 23.

The Court found that Mr. Hodge was suffering from OCD by September 28, 2004. The Court also found that Mr. Hodge's "tick exposures and subsequent Lyme disease predated his OCD symptoms." This finding is binding on remand. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1358 (Fed. Cir. 2019). There is no longer any dispute that Mr. Hodge had OCD by September 28, 2004 and he also had Lyme disease before this date.

Dr. Menzer's notes continue with the next visit on March 21, 2005. Only a portion of this note is legible. It appears to state: "sore throat, jaw pain, new stomach pains. Was taking Zolof, now off last 2 days . . ." Exhibit 3.1 at 4. Dr. Menzer appears to have written much during this visit, but neither parties' brief successfully deciphers the difficult-to-read text. This note also marks the end of Mr. Hodge's records from Dr. Menzer's office. The next medical record is on

²⁰ The rest of the note is too difficult to decode.

March 17, 2006, the date of the first hepatitis B vaccination. That medical record and subsequent medical records are discussed below in section IV.B.1.

2. School Records

Information about Mr. Hodge's schooling was sparse due to when Ms. Elson collected those records. Ms. Elson attempts to fill the gaps via testimony, discussed below in sections IV.A.4 and IV.B.3. Mr. Hodge attended various schools throughout his childhood. Some of the records have been produced; others have been destroyed or are no longer available. See infra section IV.A.3. The available and legible school records from before the 2006 vaccinations are recited below.²¹

Little information exists about Mr. Hodge's education and functioning during K-5. See exhibit 58. He attended Herrick Elementary School for kindergarten through second grade. Id. at 4. One early school record stated that Mr. Hodge's skills were below grade level. Exhibit 61 at 3. But, this notation is relatively isolated as only a few school records include grades or teachers' comments.²² He attended Knollwood School for third through fifth grade. Exhibit 58 at 4. No further information is available.

Some of the school records from the Los Angeles Unified School District were provided. See exhibit 61. Starting when he was in sixth grade (1999-2000), Mr. Hodge changed schools frequently. Id.; see also exhibit 74 (records supplied by Ventura Unified School District); exhibit 76 (some duplicates provided by Los Angeles Unified School District).

For sixth grade, Mr. Hodge attended two schools. The first was Voyager Charter School and the second was Homestead School. At both schools, his grades were all "P's" for passing. Exhibit 61 at 9.

In seventh grade, Mr. Hodge started at City of Angels School. For the first semester, he earned two A's, one B, and two C's and one grade that cannot be read with certainty. Exhibit 61 at 10. His first semester was from September 2000 to

²¹ The school records that were discovered and provided have some problems. Like many of the medical records, they are difficult to read due to handwritten notes, smudging, and suboptimal copying quality. Additionally, they are incomplete: some years have available grades; most years do not have grades. Thus, using grades as a proxy for Mr. Hodge's functioning and/or mental health is difficult.

²² Furthermore, this record is difficult to read.

February 2001. The records indicate he did not finish the second semester at this institution.²³ Although an affidavit fills in some of the gaps and is discussed below, no other records existed discussing eighth grade.

In ninth grade (October 2002-January 2003), Mr. Hodge is listed as enrolled in the City of Angels School. Id. However, no grades are listed.

It appears that for tenth grade (ending in June 2004), he attended City of Angeles School. Exhibit 61 at 7.²⁴ He received all A's and one B. Id. Mr. Hodge was 16-17 years old during tenth grade.

School records do not exist regarding Mr. Hodge's schooling for eleventh and twelfth grades. The Court determined that the lack of school records for eleventh grade supported a finding that Mr. Hodge was suffering from OCD by September 28, 2004. Second Opinion and Order, 164 Fed. Cl. 633, 647 (2023). Again, this finding is accepted. Information about his education during those years is provided via affidavits from Ms. Elson and is discussed below

3. Unavailable Records / Unsuccessful Records Request

Ms. Elson and her attorneys attempted to get records to fill in the gaps at various points. Unfortunately, not all attempts were successful. As such, some alleged events do not have any corroborating contemporaneous records. In the fall of 2018, Mr. Hodge's attorney attempted to get several records that either did not exist or no longer existed. The unavailable records regarding events prior to 2006 are recounted below.

One example was school records, including transcripts and potential IEP documents, from Nordhoff High School. Exhibit 60. The school's registrar stated she was unable to locate records of Jeremy Hodge and could not confirm that he was a student at Nordhoff High School. Id. The registrar stated that the school retained transcripts and IEPs of any students within the Ojai Unified School district (with the exception of Chaparral High School) and that all records would have been retained with no intention of destruction. Id. If other school records existed, they were destroyed. See exhibit 77.

²³ An affidavit, discussed below in section IV.A.4.a(5), revealed that Mr. Hodge did an independent study program through Somis Union School District. No records were available from that institution. Exhibit 71 at 1-2; see also exhibit 60; Tr. at 165.

²⁴ Although "tenth grade" is not written on the school record, the entry follows "ninth grade" and is two years before the completion of high school.

Mr. Hodge's attorneys also requested records from John Nasse, the doctor who prescribed Adderall to Mr. Hodge. In a handwritten note, Dr. Nasse certified that Mr. Hodge was his patient "on + off for a year between 2000 [and] 2003." See exhibit 70. Dr. Nasse wrote Mr. Hodge "was being treated for 'OCD'". Id. However, Dr. Nasse claimed the records were destroyed a couple years before the records request. Id.

Records for a facility called "Valley Care" were never discovered or filed. See exhibits 72 and 88. Valley Care is where Mr. Hodge allegedly was first diagnosed and treated for OCD.

4. Testimony

The following section is divided into two subparts. First, events from before 2006 are extracted from the six affidavits Ms. Elson submitted. Ms. Elson was the only percipient witness to submit affidavits. Mr. Hodge did not submit any affidavits. Next, Ms. Elson's oral testimony given during the hearing about details from before 2006 is summarized.

a) Ms. Elson's Affidavits

The affidavits describe events before 2006, contemporaneous with the vaccines and events after 2006. As previously discussed, this section IV.A.4.a. only recounts the content describing events before Mr. Hodge was vaccinated in 2006.

(1) Affidavit # 1 (exhibit 9)

Ms. Elson submitted her first affidavit on January 14, 2011. See exhibit 9. This date is approximately 2.5 years after the petition was filed. She recounts that Mr. Hodge "was at all times before his vaccination, extremely healthy." Id. at 1. She notes allergies, symptoms of sinus congestion, clogging, and headaches. Id. Ms. Elson sought allergy testing and medication to help with his symptoms. Id. at 1-2. She recounts that Dr. Rodriguez prescribed Nasonex and Amoxicillin. Id. at 2.

Notably, this initial affidavit makes no mention of OCD or ritualized behaviors. It generally portrays Mr. Hodge as completely healthy prior to the 2006 vaccinations. However, by the date of this affidavit, doctors had proposed that Mr. Hodge suffered from Lyme disease. Exhibit 7.1 at 45-46 (Aug. 4, 2009). The Court found that by the 2006 vaccinations, Mr. Hodge was suffering from OCD for at least 17 months and from Lyme disease for longer.

(2) Affidavit #2 (exhibit 19)

Ms. Elson submitted her next affidavit on October 1, 2014. In this filing, more details are alleged about Mr. Hodge's health prior to 2006. The affidavit begins: "While we do not know the exact trip where Jeremy likely contracted Lyme disease, we would go camping all the time at Big Sur, near my grandparents' house. . . . On our last trip there was a large amount of ticks everywhere." Exhibit 19 at 1. She recounts that there were "always ticks on the pets, and there were a lot of deer and there were ticks on everything." *Id.* She recalls that Mr. Hodge had a bull's-eye rash on his leg at the end of the (unspecified) trip.²⁵ *Id.* She alleged "[w]ithin a year of that he began exhibiting OCD hoarder symptoms and complained of spaciness and foginess in his brain." *Id.*²⁶

Although this affidavit maintains Mr. Hodge was active and participating in normal childhood activities (hiking, riding bikes, swimming, playing video games), it implicitly acknowledges he was not perfectly healthy. In contrast with the prior affidavit, this filing alleged Mr. Hodge developed Lyme disease, had "OCD hoarder symptoms" and was experiencing brain fog before the vaccinations.

(3) Affidavit #3 (exhibit 21)

In the next affidavit, filed on October 16, 2015, Ms. Elson alleged more details about her son's health pre-vaccination. Petitioner prevailed on a motion for review, and at the time of this affidavit's filing, Ms. Elson was trying to support a finding in favor of equitable tolling.

She stated: "Jeremy's OCD developed around age 16. Before about May 2006, my son acted on his OCD symptoms but he could participate in his life." Exhibit 21 at 1. She noted the same hobbies as in the prior affidavit. In this affidavit, Ms. Elson adds:

Before the vaccine he engaged in various rituals; he avoided walking in circles—circles were bad. He avoided certain numbers—numbers were scary. He walked up and down the stairs numerous times until 'he felt like he had done it the right number.' He chanted words in certain rituals and patterns. Jeremy turned the

²⁵ This affidavit does not state in what year or at what age Mr. Hodge allegedly developed the rash and/or Lyme disease.

²⁶ Similarly, the affidavit does not state in what year or at what age Mr. Hodge allegedly began experiencing OCD symptoms.

TV on and off; on and off; on and off. Same with the stove—he would turn it on and off; on and off in these rituals. His feelings told him the appropriate number of turns, of clicks, of trips he needed to take up and down the stairs. Although Jeremy struggled with OCD he didn’t hallucinate like he did after the vaccine. His habits were pure obsessions where he had to perform his rituals in the appropriate numbers but his OCD did not consume his life.

Id. Ms. Elson continues by discussing Mr. Hodge toward the end of 2005. She stated that he was on track to get his GED at that time, but he could not attend school with the rest of his peers and instead took classes through an independent study program. Id. She further alleged that due to “his condition, ordinary high school overwhelmed him.” Id.

(4) Affidavit #4 (exhibit 26)

This affidavit (filed December 4, 2015) is not relevant for this portion of the decision.

(5) Affidavit #5 (exhibit 71)

Ms. Elson filed another affidavit on November 26, 2018. See exhibit 71. This affidavit provides more details and includes references to exhibits.

She fills in some details about which schools Mr. Hodge attended between kindergarten and sixth grade. Id. at 1. She notes that they moved to Seneca Street in Ventura when Mr. Hodge was in sixth grade, and he completed the first semester of sixth grade at the Voyager Charter School and the second semester of sixth grade at Homestead School. Id.; see exhibit 61 at 9. After sixth grade, they moved to Acadia Place in Ventura where he completed the first half of seventh grade at the City of Angels Junior High and the second half of seventh grade via independent study through Somis Union School District.²⁷ Id. Ms. Elson acknowledged that records supporting this assertion do not exist. Id. at 1-2; see exhibit 60. She stated he did independent study at the Homestead School for eighth grade. Exhibit 71 at 2. She stated he attended ninth grade at the City of Angels school. Id.

²⁷ Based on the information provided, the move and seventh grade would have been between fall 2000 and spring 2001.

Ms. Elson recalled that on April 30, 2003, they moved to Canoga Park and the two lived there subsequently. Id. She stated: “I don’t remember when Jeremy had the tick bite that resulted in the bull’s-eye rash on his leg, but I think it was shortly before we moved to [Canoga Park]. It was some time after the move when he started having OCD symptoms.” Id.

Ms. Elson next states that she took Jeremy to Valley Care, where he was prescribed Prozac and then Zoloft, and was seen by treaters there on and off for about six months. Id. She stated he had OCD symptoms, but they did not interfere with his daily life. Id.

Jeremy continued at City of Angels for tenth grade and received good grades. Id.; see also exhibit 61. Ms. Elson states “Clearly, Jeremy’s OCD was not causing any problems with his school work.” Exhibit 71 at 2. She notes that she took Jeremy to Dr. Menzer in March of 2004 for sinus pressure. Id.; see supra section IV.A.1.

Ms. Elson states Mr. Hodge did independent studies throughout the school district for eleventh grade, differentiating this from home schooling. Exhibit 71 at 2. She recalls that he reported to a facility called Opportunities for Learning on Ventura Boulevard in Encino. Id. However, “Jeremy decided to drop out of high school and work on getting his GED[.]” Id.

Ms. Elson states that on March 17, 2006 (the date of the first hepatitis vaccination), Jeremy “did have OCD, and he was somewhat depressed, but he was active and enjoying” previously discussed activities. Id. at 3. She compared him to the character from the TV series Monk, stating he had OCD but could live his life. Id.

(6) Affidavit #6 (exhibit 86)

The final affidavit was filed on February 3, 2021. This lengthy affidavit featured specific questions posed by the undersigned. Though a majority of the questions were answered, at times the responses to multiple questions were condensed into a single response. Ms. Elson testified that she generally relied on her memory when creating the prior affidavits but also referred to some exhibits. Exhibit 86 at 1.

She discussed her family health history. Exhibit 86 at 2-5. She stated that Jeremy’s father had head injuries, resulting in personality change. She and Jeremy’s father separated when Mr. Hodge was 16; Ms. Elson and Jeremy moved away around 2003. Id. at 4-5.

Ms. Elson was asked questions regarding her employment. See id. at 5-6. She recalled working on and off, waitressing, working in movie theatres, and modeling before Mr. Hodge was born. Id. at 5. Ms. Elson could not recall the specifics of the odd jobs she worked between 2004 and 2009. Id. at 6.²⁸ She discussed the activities she enjoyed. Id. at 6-7.

Next, Mr. Hodge's schooling was recounted. Id. at 7-9. Ms. Elson listed the schools he attended for K-5. Id. at 7-8. She affirmed he went to Voyager Charter School and the Homestead School for sixth grade, which he completed in June of 2000. Id. at 8. Next, he attended City of Angles Junior High and did independent study through Somis Union School District for seventh grade. Id. For eighth grade, he did independent study again at Homestead. He returned to City of Angels for ninth and tenth grade. Eleventh grade involved independent study through the school district and Opportunities for Learning in Encino. Id.²⁹

The next portion of the affidavit concerned Mr. Hodge's activities and interests. Id. at 9-10. Ms. Elson recounted Mr. Hodge enjoyed hiking, riding bikes, numerous sports, WWE wrestling events, and playing video games with friends. He enjoyed being outdoors. He performed one or more of these activities almost every day. Id. at 10.

The following section of the affidavit involves questions about Mr. Hodge's health between 2003 and March 17, 2006. Id. at 10-13. Ms. Elson recounts that during this period, he did not have any problems related to his sense of touch and he did not have excessive or unusually frequent headaches. Id. at 10. He slept easily and did not have problems walking. Id. at 11. When asked if professionals other than Dr. Menzer provided Jeremy any medical care, Ms. Elson wrote: "I can't remember. He may have seen professionals for OCD, perhaps Dr. Nasse." Id. She assessed Dr. Menzer as a good doctor. She recalled that Dr. Nasse prescribed the Adderall in 2004 and stated she did not give the medication to Mr. Hodge as prescribed. Id. at 11-12.

She stated Mr. Hodge was first diagnosed with OCD at Valley Care and his symptoms started sometime after their move on April 30, 2003. Id. at 12-13. She reported the OCD was apparent due to his various rituals. Id. at 13. In this

²⁸ In response to the question of where she was employed, she wrote: "I don't remember specifics. It was a long time ago." She also could not recall her earnings or identify any work colleagues, co-workers, or supervisors.

²⁹ Some school records were obtained and filed, as noted in the affidavit. See exhibit 58 and exhibit 61. Good grades were noted in tenth grade. Exhibit 61 at 7. Other records were found to be unavailable. See supra section IV.A.3.

affidavit, she states Valley Care treated him with Prozac and then switched him to Zoloft. Id.

b) Ms. Elson's Oral Testimony

In addition to the affidavits, Ms. Elson testified during the June 14, 2021 hearing. She reviewed her affidavits and some of the records in preparation. Tr. at 144.

When asked to describe Mr. Hodge's general health from birth to age 16, she stated he was "very healthy." Id. She testified that during a camping trip with lots of ticks, Mr. Hodge received a bull's-eye rash and subsequently developed OCD symptoms. Tr. at 144-45. She recalled the OCD symptoms started at around age 16 and he received an OCD diagnosis at age 17. Tr. at 145. Despite the symptoms, she insisted his life was "very normal." Tr. at 146. However, he had to quit school in eleventh grade because Ms. Elson and Mr. Hodge had moved several times and "the OCD made him work a little bit slower because he would get caught up counting" and with "ritualistic behaviors." Id.

His rituals included "[a] lot of checking[.]" Id. This included turning lights, faucets, and the oven on and off, going up and down the stairs, and avoiding cracks in the sidewalks. Tr. at 146-47. On a bad day, Mr. Hodge would spend about 20% of his day consumed by OCD symptoms. On good days, it was not noticeable. Tr. at 147. She recalled Mr. Hodge getting OCD treatment at Valley Care but could not remember the name of the doctor that diagnosed him. Tr. at 147. She stated he was on Prozac during this time period. Id. Ms. Elson estimated she took Mr. Hodge to Valley Care about four or five times between 2003 and 2004. Tr. at 202.

During cross-examination, Ms. Elson was asked about whether Mr. Hodge was seeing other doctors or receiving other treatment at around age 16 when the OCD symptoms purportedly started. Tr. at 161. Ms. Elson responded: "It's kind of hard to remember. Everything is so – just such a blur now. I may have, about that time, gone to Dr. Nasse, but other than that, I'm sorry, I don't remember." Id. She could not recall, without checking her notes, what grade Mr. Hodge was in when she separated from Mr. Hodge's father. Tr. at 165-66. "The dates are very fuzzy for me right now. It's just been so long." Tr. at 166.

After being reminded that Mr. Hodge was placed on Adderall in 2004, Ms. Elson noted that Mr. Hodge took Adderall only one time. Tr. at 163. She stated she did not fill the prescription. Tr. at 170. She could not remember if Dr. Nasse prescribed any other medication and thought Mr. Hodge saw him only twice. Tr. at 167. She recalled Mr. Hodge taking Zoloft for a couple of weeks in 2005. Tr. at 170. But, it was "hard to remember all the medications." Tr. at 171.

Respondent's counsel asked Ms. Elson if she had any recollection of the month or year that the Big Sur camping trip took place. She responded: "I know it was not – I know it wasn't – maybe spring. I'm literally guessing. . . . It would have been like summer or spring, something like that." Tr. at 192-93. She proceeded to say Mr. Hodge was about 14 or 15 years old on that trip (which would be between 2001 and 2003). Tr. at 193.

5. Expert Commentary

The petitioner submitted several expert reports. Most of the content of these reports focus on Mr. Hodge's health in 2006 and beyond. Some opinions were generated about Mr. Hodge's health prior to the 2006 vaccinations. These opinions were based on the medical records and affidavits available to Dr. Tornatore at the time of each report.

a) Dr. Tornatore's First Expert Report

Ms. Elson filed Dr. Tornatore's first expert report on August 23, 2013. Exhibit 18. This report largely focused on records from 2009, three years after Mr. Hodge's hepatitis vaccinations, as limited records were available to him at this time. Based on medical records from 2009, in which doctors attempted to understand Mr. Hodge's past and had to rely on histories provided by Mr. Hodge and Ms. Elson, Dr. Tornatore opined that Mr. Hodge began experiencing "some symptoms (progressive fatigue, headaches, memory disturbances, myalgias)" in 2005. *Id.* at 2. Working with the records available to him at that time, he estimated the neuroborreliosis onset was in 2005. *Id.* These are the only aspects of Mr. Hodge's pre-vaccination health discussed in this report.

b) Dr. Dasher's Expert Opinion

The next report submitted by Ms. Elson was from Dr. Robert Dasher, a psychiatrist. Exhibit 22. This report was filed on October 16, 2015. It does not address Mr. Hodge's pre-vaccination health history, as it predates his care and treatment of Mr. Hodge. Thus, this report will be discussed in the section regarding health after the 2006 vaccines.

c) Dr. Tornatore's Second Expert Report

Ms. Elson filed Dr. Tornatore's next report on January 23, 2017. Exhibit 29. By this time, petitioner's counsel had developed the evidence a little more, but not substantially. The only pre-vaccination health history discussed in this report is Mr. Hodge's March 10, 2004 visit to Dr. Menzer, in which he complained of sinus pressure for two months. *Id.*; *see* exhibit 3. Again, based on the information

available at that time, Dr. Tornatore opined that Mr. Hodge “contracted Lyme disease in 2005” and developed symptoms of OCD shortly thereafter. Exhibit 29 at 7. Most of this report contains commentary on Mr. Hodge’s health after his 2006 vaccinations and medical theories regarding his condition. See generally id.

d) Dr. Tornatore’s Third and Fourth Expert Reports

Ms. Elson filed supplemental reports authored by Dr. Tornatore on December 18, 2017 (exhibit 34) and April 30, 2018 (exhibit 35). Due to the issues being litigated at the time of these reports, the reports do not discuss Mr. Hodge’s health before the 2006 vaccinations.

e) Dr. Tornatore’s Fifth Expert Report

The fifth and final report from Dr. Tornatore was filed on October 26, 2020. Exhibit 83. Although this report is more comprehensive, the only pre-vaccination medical record discussed is the March 10, 2004 record from Dr. Menzer. Id. at 1, passim. Within the report, the March 10, 2004 record serves as a baseline of comparison. Dr. Tornatore notes that Mr. Hodge did not have subjective reports of neurologic symptoms or objective testing supporting neurologic issues on that date. The remainder of the report considers evidence from the date of the first vaccination onward.

f) Dr. Tornatore’s Oral Testimony

During the hearing, Dr. Tornatore did not testify much about events prior to the 2006 vaccinations. His assertions about what may have happened prior to 2006 depend on the sparse medical records and the testimony provided by Ms. Elson.

Based on the March 17, 2006 medical record (exhibit 5 at 2), Dr. Tornatore opined Mr. Hodge was diagnosed with OCD in 2005. Tr. at 15. He further opined that Mr. Hodge had neuroborreliosis, which caused the OCD. Id. at 16-17. When asked when Mr. Hodge developed neuroborreliosis, Dr. Tornatore relied upon later created medical records and Ms. Elson’s affidavits. Id. at 21. He opined “it sounds like there was a trip where they were camping and it sounds like multiple people in the family were exposed to ticks. And so it clearly was somewhere perhaps in that time. Maybe it was after that.” Id. Based on the notation that Mr. Hodge had OCD when he was 17, Dr. Tornatore opined the neuroborreliosis must have started earlier in order to cause the OCD. Id. at 21-22. “It’s hard to know . . . when that [tick] exposure was, but it clearly preceded the documented OCD” Id. at 23.

Aside from the affidavits, Dr. Tornatore reached his opinion that Mr. Hodge had neuroborreliosis by utilizing MRIs and spinal fluid data from 2009, discussed below, along with medical literature. Tr. at 16-17.

g) Dr. Venkatesan's Commentary

Dr. Venkatesan wrote that “the onset of Mr. Hodge’s symptoms during adolescence/ early adulthood and the waxing and waning course would be quite typical of OCD.” Exhibit E at 4. Dr. Venkatesan proposed that Mr. Hodge’s OCD was separate from (not caused by) his Lyme disease. Id.

In Dr. Venkatesan’s oral testimony, he discussed the sparseness of the pre-vaccination medical records. Tr. at 349; see also id. at 351 (noting the lack of records from West Valley and Dr. Nasse), 431 (same). Dr. Venkatesan did agree that Mr. Hodge suffered from OCD before the vaccination. Id. at 349. Due to the lack of information in medical records, Dr. Venkatesan could not opine on the severity of Mr. Hodge’s OCD. Id. at 430.

Dr. Venkatesan stated that he did not see indications that Mr. Hodge suffered from Lyme disease before 2006. Tr. at 352. He also did not see evidence that Lyme disease caused Mr. Hodge’s OCD. Id. at 369.

6. Fact Findings by the Court

The Court has found that “(1) Mr. Hodge exhibited symptoms of OCD by September 28, 2004, and (2) Mr. Hodge’s tick exposures and subsequent Lyme disease predated his OCD symptoms.” These findings are binding.

B. Mr. Hodge’s Health During and After the Vaccinations

The following section concerns Mr. Hodge’s health from the date of the first vaccination onward. Information is derived from (1) medical records; (2) statements and evidence regarding missing and unavailable records; (3) testimony from affidavits and oral statements; and (4) expert commentary.

1. Medical Records

The following sections recite the pertinent (available) medical records concerning Mr. Hodge’s health following his vaccinations in 2006.

a) Mr. Hodge’s Health in 2006

(i.) First hepatitis B vaccination

On March 17, 2006, at the age of 18, Mr. Hodge appeared at Noble Community Choice Provider Medical Group (“Noble Clinic”) for an adolescent health maintenance exam. Exhibit 5 at 2. The treating doctor was Jorge Rodriguez. Someone told Dr. Rodriguez that Mr. Hodge was feeling pressure in his face.³⁰ One line reads: “(+) OCD started at 17yrs.” Id. Another line states: “mother [unintelligible] at cognitive therapy.” Id. The record also states: “[Family] [history]: . . . father = ADD, grandmother = ? OCD”. Id.³¹

Physical exams and a neurologic assessment from this visit were all documented as normal. Id. Mr. Hodge weighed 159 pounds. Id. Dr. Rodriguez’s assessment of Mr. Hodge included allergic rhinitis, OCD, and possibly sinusitis. He prescribed Amoxil and some other medication. At this March 17, 2006 appointment, Mr. Hodge received the hepatitis A and hepatitis B vaccinations. Id. at 2, 7.

A “‘STAYING HEALTHY’ ASSESSMENT” was completed at this visit. Id. at 5. Generally, it discloses healthy habits. However, “Yes” was marked next to the question about whether Mr. Hodge “Often feel[s] sad, down, or hopeless[.]” Id. The assessment form also notes that medication was used “sometimes” to sleep, relax, calm down, feel better, or lose weight, with “OCD” added in for context. Id. at 6. Additional questions or concerns about health were noted, which included “sinus pain, allergies?” Id.

(ii.) Second hepatitis B vaccination

The next medical record is from April 25, 2006, when Ms. Elson brought Mr. Hodge back to the Noble Clinic for a follow-up visit. Exhibit 5 at 3. The intake notes suggest Mr. Hodge was seeing a psychiatrist or psychologist, though the doctor’s name is not legible. Id. The note states Mr. Hodge was on Zoloft, his mom did not want him taking that drug, and that his mom was concerned about toxoplasmosis. Id.³² Samples were taken, which were negative for toxoplasma AB IgG. Id. at 10. He weighed 155 pounds at this visit. Id. at 3.

³⁰ Throughout Mr. Hodge’s medical history, the historian who reports symptoms to medical personnel is not always clear. The historian could be Ms. Elson sometimes. See Exhibit 8.5 at 76, Exhibit 19 at 2, Exhibit 26 at 1.

³¹ As with other medical records in this case, this record contains difficult-to-read handwriting. Some aspects are illegible.

³² Much of the notes from this visit are illegible. See Pet’r’s Posthear’g Br. at 9 (acknowledging that the record cannot be deciphered completely).

Subjective complaints from the April 25, 2006 visit included uncontrollable eye movement, neck pain, facial pressure, and itchiness.³³ Id. at 3. However, abnormal neurologic signs (as opposed to complaints) do not appear to have been documented on this medical record. Mr. Hodge received the second dose of the hepatitis B vaccine.

(iii.) Valley Presbyterian – June 2006

Mr. Hodge's next visit to a hospital was thirty-eight days later, on June 2, 2006. He presented to the Valley Presbyterian Hospital emergency room. Exhibit 6.1 at 7. The chief complaint was "Dizzy / Eye movement disturbances." Id. The history of present illnesses section states that complaints included "back pain, joint + muscle aches and fatigue since receiving Hep B & A vaccinations 4 [months] ago. Blood tests done = normal per mother." Id. The review of systems indicated problems with fatigue, nasal discharge, bone/joint pain, back pain, headaches, dizziness, and frontal room spins. Id. The physical examination memorializes that Mr. Hodge was "Oriented X 3" with memory intact, and that he was well nourished. Id. A flat affect was noted. An additional note was added that Mr. Hodge had a negative vertical/horizontal nystagmus test.³⁴ Id. The neurological examination was within normal limits. Id.

At this June 2, 2006 visit, Mr. Hodge received a CT brain scan without contrast enhancement. Id. at 4, 10. The record notes a history of headaches. The impression note for the CT scan was "Normal." Id. at 4. A diagnosis from the visit was that Mr. Hodge had neurological problems without specifying the nature of those neurologic problems. Id. at 2. Impression notes listed "dizziness" and "arthralgias – myalgias s[tatus]/p[ost] Hepatitis vaccination." Id. at 6. Mr. Hodge was discharged that day, with his condition "Improving" and "Good." Id. He was given Meclizine.³⁵ Id.

³³ The information appears in the portion of the form for "subjective" material. The handwriting in the "objective" portion is illegible. See Second Opinion and Order, 164 Fed. Cl. 633, 640 n.10 (2023).

³⁴ Nystagmus is "an involuntary, rapid, rhythmic movement of the eyeball, which may be horizontal, vertical, rotatory, or mixed." Dorland's at 1289.

³⁵ This medication treats dizziness and nausea. See Dorland's at 1102 (defining meclizine).

Ms. Elson called the Noble Clinic on June 8, 2006. Exhibit 5 at 4. The phone note appears to read:

Mother called and was very upset about neurologist and according to mother neurologist was very rude and didn't know Zoloft was used for OCD and she did not trust him. Mom concerned about vit. B deficiency and was pushing for MRI for Jeremy. Informed mom will do MRI request and not^[36] get CT scan fr[om] Valley Presbyterian. [Three illegible words]. Informed mother will report to VAERS if [illegible] vaccine related adverse effect.

Id.³⁷

(iv) Encino/Tarzana – August 2006

More than two months passed before Mr. Hodge's next medical appointment. On August 22 and 23, 2006, Mr. Hodge presented to the emergency department at Encino-Tarzana Regional Medical Center. Exhibit 4 at 2-15.³⁸ On August 22, 2006, he was evaluated by Dr. Ralph Baca and complained of diffuse paresthesias. Id. at 12. The note memorialized that "[t]he patient state[d] these symptoms have been evident intermittently since receiving [the] hepatitis vaccine earlier this year. The mother also state[d] that she [was] concerned that the patient, her son, appears more jaundiced, and also complains of dizziness associated with generalized weakness." Id. Mr. Hodge denied any depression, anxiety, or hallucinations. Id. Mr. Hodge's eyes were examined and normal at that time. Id. at 13. A chemistry panel, thyroid study, and urinalysis were ordered, with normal results. Id. He was discharged as stable. The diagnostic impression was "Neuropathy, etiology uncertain." Id.

³⁶ This word was difficult to decipher, but according to petitioner's brief on page 10, petitioner decoded "not."

³⁷ This difficult-to-read note was mostly deciphered by petitioner. See Pet'r's Post Hearing Br. at 10.

³⁸ In referencing this exhibit, petitioner wrote as though there was no August 22, 2006 visit, only a visit on August 23, 2006. Pet'r's Posthear'g Br. at 10. Respondent treated the record as referencing two visits, August 22 and August 23, 2006. Resp't's Posthear'g Br. at 10-11. It is possible that the reference to August 22, 2006 in the record was a mistake and that there was only one visit. It is also possible there were back-to-back visits.

Mr. Hodge was seen in the emergency department the next day, August 23, 2006. Id. at 2. The record notes Mr. Hodge stated, “it’s hard to feel my skin” and indicates his “mom state[d] it all started p[ost] Hepatitis vaccine.” Id. at 4. OCD was recorded under medical/social history. Id. The neurological assessment listed Mr. Hodge was alert and oriented “x 3”. Id. Mr. Hodge weighed 160 pounds at this visit and the record states his skin color was normal rather than pale, flushed, or jaundiced. Id.

(v) UCLA – November 2006

Mr. Hodge’s next encounter with medical professionals was on November 3, 2006, when he arrived at the UCLA emergency room. Exhibit 67 at 1-10; see also exhibit 32 at 26-35 (duplicate). The chief complaint was decreased sensation to skin for seven to eight months, as well as facial pain and inability to relax. The review of systems indicated he had depression but did not have weight loss. Exhibit 67 at 2. The record indicates Mr. Hodge was awaiting a psych evaluation but left prior to being assessed. Id. at 5. The discharge impression was OCD and numbness. Id. at 3.

(vi) Mr. Hodge’s Health in 2007 – 2008

The parties stated that between November 2006 and July 2007, there are no available medical records. See Pet’r’s Posthear’g Br. at 11; Resp’t’s Posthear’g Br. at 11.

However, a more thorough search for records also led to the discovery of medical records from the emergency department of Providence Saint Joseph Medical Center on June 20, 2007. Mr. Hodge was seen for “depression, numbness to both hands.” Exhibit 65 at 2. The chief complaint was “[Patient] has multiple psychological problems x ‘months’ [complains of] physical ‘pain.’ Sudden onset on & off x ‘months.’” Id. The history of present illness recounts his history of problems: “Mother states that over the last year, he has had numerous symptoms including headache and chest pain, his Adam’s apple appears to be large, shortness of breath, numbness and tingling in his extremities, weight loss, difficulty eating, back pain, and uncontrollable fits. She describes this and many numerous somatic complaints.” Id. at 5. The June 20, 2007 record notes Mr. Hodge’s vitals and states Mr. Hodge was “a well-developed, well-nourished male.” Id.

The history of present illness also presents Ms. Elson’s account of her efforts to obtain medical care.

Mother states that she has been to many emergency departments and clinics. Labs have been done, which showed no abnormalities. She states that approximately 1 year ago he had a head CT, which showed no abnormalities. Otherwise, she is here requesting a neurologic evaluation and MRI. She states that she has not been able to receive any authorizations from her insurance. . . . The patient himself denies any acute complaint at this time.

Id.

Upon examination, the doctor from the emergency room, Lawrence E. Wells, recorded Mr. Hodge was “in no acute distress. He [was] awake, alert, and oriented to person, place, and time. . . He [was] able to ambulate up and down the hallway without any difficulty whatsoever.” Id. Dr. Wells stated that he “advised the mother that [Mr. Hodge’s] symptoms appeared to be somatic signs of severe major depression and anxiety.” Id. at 6. Dr. Wells also “strongly advised the mother that she needs to follow up at one of the County Facilities if she is unable to follow up with a neurologist and I have told the mother that my suspicion is that the patient has somatization of his psychological problems.” Id.³⁹

On July 10, 2007, Mr. Hodge presented to West Valley Mental Health Center for an Adult Initial Assessment. Exhibit 11 at 2-12, 14-16. Under Presenting Problem / Chief Complaint, the form states:

[History]: OCD: 2 [year] [history] of tapping, touching, counting, stress [with] environment made it worse.
[History] of depression. Took Zoloft (4 [weeks]) made him worse, Prozac made him feel suicidal, racing thoughts [with] counting. No current S[uicidal] I[deation]. Not sleeping, argumentative at times. No good sleeping, naps during day. Sometimes sleeps too much. Very pale (+) psychosis, seeing shadows. ‘It’s bad air, environmental.’

Id. at 3. The form states Mr. Hodge had only completed 10th grade. It additionally notes Mr. Hodge’s dad was bipolar and had ADD, and that his grandmother was a

³⁹ At Ms. Elson’s request, Dr. Wells obtained an imaging study of Mr. Hodge’s sinuses, which was normal. Exhibit 65 at 7. Other than mentioning that Ms. Elson was requesting an MRI, Dr. Wells’s note does not discuss whether an MRI was appropriate. See exhibit 65.

hoarder, suggesting a “strong family h[istory] [of] mental illness.” Id. Under medical history, the record indicates no problem with “weight/appetite ch[an]g[e]”. Id. at 4. The record indicates he was taking Xanax, prescribed by Dr. Nasse. Id. at 3, 4. The diagnostic summary stated Mr. Hodge had a history of psychosis and OCD since age 16. Id. at 8. Medical case management was recommended. Id. He did not return for treatment. Id. at 13.

The next available medical record is from West Hills Hospital and Medical Center on September 9, 2007. Exhibit 8.5 at 76. Mr. Hodge was evaluated by Dr. Alan Kuban. Dr. Kuban wrote that Mr. Hodge was brought in by his mother “for evaluation of chest pain, OCD problems, [and] palpitations.” Id. Dr. Kuban observed Mr. Hodge was a vague historian and that Ms. Elson “almost controls his situation and provides the history.” Id. Ms. Elson related that Mr. Hodge had been complaining of chest pain for over 6 months and had intermittent throat infections. Id. Dr. Kuban noted Ms. Elson also conveyed that Mr. Hodge had “a significant change in his personality over the last 18 months. She believes this may be related to previous hepatitis vaccinations.” Id. at 76-77. Dr. Kuban opined Mr. Hodge “clearly has significant impairment due to his OCD.” Id. at 77. He recommended a neurologic consultation.⁴⁰ Id.

Mr. Hodge received mental health therapy at San Fernando Valley Community Mental Health Center (“Transitional Youth”) on a somewhat regular basis between November 2007 and February 2008. See exhibit 10. He received psychotherapy treatment, as well as numerous medications, including Risperdal, Lithium, Ativan, and Fluoxetine. Id. at 3, 59, 65. An initial assessment was that he suffered from OCD. Id. at 9. Concerns were expressed about the medications and services provided. See generally id. Attendance became less frequent in the spring and summer of 2008. After no contact for several months, on September 16, 2008, Transitional Youth closed Mr. Hodge’s case file. Exhibit 10 at 8.

The Pfeiffer Treatment center performed a urinalysis for Mr. Hodge in March 2008. See exhibit 57. Malabsorption and low histamine levels were reported. Id. at 2. Diet and nutrition changes were recommended. Id. at 7, passim.⁴¹

⁴⁰ Citing to exhibit 8 at page 77, respondent’s post hearing brief states that a neurologic consultation was not recommended. Resp’t’s Posthear’g Br. at 13. This assertion is inaccurate. See exhibit 8.5 at 77 (“I do recommend neurologic consultation”).

⁴¹ Subsequent testing in February 2009 showed high levels of kryptopyrrole in Mr. Hodge’s urine.

Mr. Hodge arrived at the West Hills Hospital emergency room on December 4, 2008, with a chief complaint of a lesion on his left thigh and left eyelid. Exhibit 8.2 at 25. Past medical history listed him as bipolar, and suggests he was taking Risperdal and lithium at that time. Id. The treater considered the left thigh rash to be consistent with ringworm. Id. He was discharged in a stable condition.

b) Mr. Hodge's Health in 2009 – MRIs and Lyme Disease Diagnosis

Mr. Hodge was seen at Olive View / UCLA Medical Center (“Olive View”) in February 2009. Exhibit 7.1 at 8. Chronic headaches were reported. Id. at 5-8. Under the neurologic assessment, the record notes Mr. Hodge was oriented, and his gait was within normal limits, though sensory issues were discussed.⁴² Id. at 8. Though the handwriting is difficult to discern, it appears that follow-up appointments with neurology and an MRI were ordered. Id.

On May 19, 2009, an MRI was performed on Mr. Hodge's brain at the Olive View. Exhibit 2; exhibit 7.2 at 210-11. The study's findings note:

Multiple white matter hyperintensities are seen in the periventricular, deep and subcortical white matter, one of which on FLAIR axial image 14 of series 4 has its long axis parallel to the long axis of the ventricles, I suspect the presence of demyelinating disease although the patient is a young male rather than a young female. Evaluation with contrast was not requested and not done and no history is provided. The differential diagnosis for the above white matter hyperintensities does include gliosis, migraine headaches, collagen vascular disease, vasculitis or ischemic change which would be too early in this patient. The brainstem is unremarkable.

Exhibit 2.⁴³ The interpreting doctor's impression was “demyelinating disease, in the absence of adequate clinical history” with “a wide differential diagnosis.” Id.

⁴² Unfortunately, the handwritten notes on this copy of the medical record are largely illegible.

⁴³ Citing to exhibit 2, petitioner's post hearing brief states that Mr. Hodge received this MRI on February 14, 2009. Pet'r's Posthear'g Br. at 8. This assertion is inaccurate.

at 2. The doctor recommended a follow-up exam with contrast using a multiple sclerosis (“MS”) protocol. Id.

On June 5, 2009, Mr. Hodge had blood drawn and analyzed for further diagnostics. Exhibit 7.2 at 209. It was notable for *B. Burgdorferi* IgG IFA with a 1:80 titer, a borderline positive result. Id. *B. Burgdorferi* IgM was <1:10. Id. These results suggested Mr. Hodge had Lyme disease. However, subsequent western blot testing on June 18, 2009 was negative for *B. Burgdorferi* IgG. Id. at 204. Additional serology tests were conducted by Dr. Mathisen, an infectious disease specialist, on September 10, 2009. Exhibit 63 at 1. The results were negative / inconclusive. Id.

Mr. Hodge was evaluated by a resident in the neurology department at Olive View on August 4, 2009. Exhibit 7.1 at 45-46. He had “nonspecific complaints (headache, intermittent arm numbness, neck/back spasms)” and the resident also noted “psychiatric [disorders] including OCD behavior, bipolar vs. schizoaffective [disorder] all of varying onsets starting at age 17.” Id. at 45. The chief complaint / history of present illness section discussed Mr. Hodge’s medical history.⁴⁴ Id. at 44. The record states Mr. Hodge “was normal prior to age of 17, abrupt onset OCD-like behavior (counting, checking, etc) over 1 month, then onset of a mental ‘fogginess’ / ‘detachment from reality’ of insidious onset that has since waxed and waned with periods of ‘normalcy’.” Id. at 46. It further states Mr. Hodge received his routine hepatitis B vaccine at 18.5 and that he experienced subsequent stabbing pain, and muscle and skin tightness with spasms of gradual onset. The record recounts a tick exposure, and that Ms. Elson was convinced the symptoms were secondary to the vaccine. Id. The assessment notes differential diagnoses, including “MS, Lyme d[isease], post vaccination demyelinating d[isease], other demyelinating d[isease].” Id. at 45. The doctor ordered an MRI with MS protocol as well as a lumbar puncture and blood tests to rule out “MS, Lyme, other encephalitis, etc[.]” Id.

An attending doctor, Shri Mishra, added handwritten notes below that information. Dr. Mishra stated that Mr. Hodge was a “22 yr old male [with] [history] of behavioral problem starting at age 17. Pt has [history] of tick bite? Exposure to northern California Lyme?” Id. Dr. Mishra stated that Mr. Hodge

⁴⁴ Given that Mr. Hodge had not seen Dr. Mishra at the time of the recording of these notes because Dr. Mishra’s notes appear after the resident’s notes, it seems likely that this history was provided by Ms. Elson, rather than being derived from a review of records.

“has normal gen physical & neurologic exam.” Id. Dr. Mishra’s impression was “[history] of Lyme?” Id.

On August 11, 2009, Mr. Hodge received another brain MRI, with and without contrast, so that it could be evaluated for MS and compared to the May 19, 2009 MRI. Exhibit 7.1 at 65-66. The doctor’s impression was “[b]ilateral demyelinating plaques again noted on today’s exam. Plaques also present at callosal septal interface (inferior surface or [sic] corpus callosum). No abnormal enhancement.” Id. at 65. No new abnormalities were appreciated. Id. at 65.

Mr. Hodge had a CT scan of his sinuses on September 17, 2009. Id. at 64. The findings were unremarkable.⁴⁵

Mr. Hodge was seen at the Olive View – UCLA Medical Center Outpatient Clinic on September 24, 2009. Exhibit 14.4 at 457. He was seen by two people of which one was Dr. Mathisen. Id. The subjective portion accounts that Mr. Hodge was a “22 year old male with “? Lyme disease, had characteristic EM rash after went camping, on back of [right] calf 3 yrs ago. Then 6 wks after rash had ‘OCD’ type symptoms. Was given amoxicillin for a squirrel bite, then two months amox for ? sinusitis.” Id. Another portion states “went camping a few times prior.” Under family history, there is a note “(+) grandfather [with] psych problems (bipolar).” Id. For the current complaints in the subjective portion of the record, someone has recorded that Mr. Hodge was positive for lethargy and fatigue but did not have arthritis. Although presented under the heading “physical exam,” there is a note of a history of “verbal/physical abuse from father.” Id. The next line indicates that Mr. Hodge has a history of “visual hallucinations, auditory hallucinations.” Id. Under physical exam, Mr. Hodge is recorded as having “double vision” and “joint pain occasionally.” Id. There is also a notation that Mr. Hodge “doesn’t remember last OCD type symptoms or last delusions.” Id.

With respect to Lyme disease, this record presents some information.

		8/09	6/09
Lyme Ab [antibodies]	IgG:	1:160	1:80
	IgM:	<1:10	<1:10

Id. The “Lyme Western Blot” was “negative” with “1 band present.” Mr. Hodge’s MRI was noted as being positive for “(+) B/L [possibly meaning bilateral]

⁴⁵ The parties did not comment on this scan in their briefs, and the findings seem to be of little relevance.

demyelinating plaques present @ callosal septal interface.” Id. There was no “abnormal enhancement.” Id.

Under assessment / plan, a doctor wrote: “? Chronic Lyme Disease” “Some objective findings on MRI [with] (+) AB, may have been exposed in the past.” “Would recommend LP to look for evidence of [multiple sclerosis] and oligoclonal bands.” “Will consider IV ceftriaxone x 2 months +/- long term doxycycline but will need to see psych, neuropsych prior.” Id.

Mr. Hodge was seen at the Olive View-UCLA Medical Center for a neurology evaluation on September 29, 2009. Exhibit 7.1 at 44. It appears that Mr. Hodge came to this appointment because his MRI report was “concerning for demyelinating disease.” Id.⁴⁶ The record states that Mr. Hodge has no “PMH [presumably past medical history] but [patient with] OCD [symptoms], ‘bad mood swings,’ [history] of hallucinations. [Patient with history of] tick bite at Monterey County, CA. [Patient with] chronic [headache. Patient] never [diagnosed] for Lyme [disease.] [Patient complains of] chronic fatigue, [headache], joint pain.” Id. Mr. Hodge’s mental status was checked as “normal.” Id. The doctor noted that the MRI was positive for demyelinating plaques and wanted to rule out multiple sclerosis.

On October 19, 2009, Mr. Hodge had a PET scan of his brain for “suspected neurolyme.” Exhibit 7.2 at 178. The findings included “diffusely decreased metabolic activity in the cerebral cortex and basal ganglia” with non-specific distribution. Id. Additionally, “apparent hypermetabolism” was observed “near the midline in the region of the parietal lobes, [which] likely corresponds with area of prominent gyral folds seen on MRI.” Id.

On October 22, 2009, Mr. Hodge was evaluated at Olive View by psychiatrist Robert Dasher. Exhibit 7.1 at 23, Exhibit 14 at 441-47. Dr. Dasher’s summary was that Mr. Hodge had a “4-5 yr [history] of cognitive [symptoms] assoc [with] high exposure to Lyme disease.” Exhibit 14.4 at 447. For the “Presenting Problem/Chief Complaint,” Dr. Dasher wrote “‘Fog in head, memory issues, joint pains + aches throughout body.’ x 4-5 yrs. ‘Can’t remember some things I used to it’s drastic.’ Some new onset OCD [symptoms] incredible urged to touch, count.” Id. at 448. For the “Psychiatric or Mental Health Treatment History,” Dr. Dasher stated no depression and “some anxiety. Feels like everything is amplified [illegible] sounds.” Id. Dr. Dasher also noted Mr. Hodge’s use of various medications. Id. For the “Family, Relationships and Support

⁴⁶ The handwriting for this document is difficult to understand.

Systems,” Dr. Dasher indicated that Mr. Hodge lives with his mother with whom he has a good relationship. There was a positive indication of domestic violence within Mr. Hodge’s family of origin and a notation of “physical/sexual abuse → from FA.” Id. at 449. For family history, Dr. Dasher stated that a “GFa [presumably, grandfather] bipolar – reading maniac almost all his life – excess ETOH” and a “GMo [presumably, grandmother] Hoarder of books.” Id. Supportive people in Mr. Hodge’s life included his mom, friends and a current girlfriend. Id. For education, Dr. Dasher indicated that Mr. Hodge’s highest grade completed was the eleventh grade: “had to drop [because] confusion can’t think clearly.” Id. at 451. For Mr. Hodge’s “Related Medical History,” Dr. Dasher stated that Mr. Hodge had migraines which had an onset after “cognitive problems.” Id. at 452.

Dr. Dasher also completed a one-page “Mental Status Exam.” Id. at 454. For most items, Mr. Hodge was marked as being within normal limits. However, his mood was checked as being “anxious” and “angry.” Id. Dr. Dasher indicated that Mr. Hodge’s obsessions were “touching, counting.” Id. Mr. Hodge did not have delusions. Id. For hallucinations, Dr. Dasher wrote “? Visual, [no] auditory.” Id.

For “Diagnostic Impression,” under “Axis 1,” Dr. Dasher indicated Mr. Hodge had a cognitive disorder, but he could not provide further specification. Dr. Dasher also wrote: “r/o [presumably rule out] 1° OCD - current [symptoms.] r/o [presumably rule out] bipolar - vague [history plus family history].” Id. at 455. He proposed neuro-psychological testing and a follow-up visit in three weeks. Id.; see also Exhibit 7.1 at 23.

Mr. Hodge was evaluated again at Olive View on November 13, 2009, as an outpatient in the ophthalmology clinic. Exhibit 7.1 at 9. The assessment noted Mr. Hodge had an “MRI concerning for demyelinating lesions.” Id. It further stated “[no] clinical evidence of optic nerve involvement [for both eyes]. No evidence of intraocular inflammation, infection, given ? history of chronic Lyme disease.” Id.

On November 17, 2009, Mr. Hodge underwent a lumbar puncture. Exhibit 7.2 at 173-75. The cerebrospinal fluid (“CSF”) contained more than 5 well defined oligoclonal bands. Id. The report stated the bands “indicate abnormal synthesis of gammaglobulins in the central nervous system.” Id. The interpreter found this evidence supportive of a MS diagnosis but noted other clinical and laboratory data were necessary for clarification. Id. *B. burgdorferi* was not detected in the CSF sample. Id. at 173.

Mr. Hodge was seen at the infectious disease clinic of the Olive View – UCLA Medical Center on December 3, 2009, by two people including Dr. Mathisen. Exhibit 7.1 at 22. The subjective portion of this record begins with a note that Mr. Hodge was “[presumably, “sine,” meaning “without”] past medical history presents for evaluation of Lyme Disease. [Patient] was in his normal state of health until ~4 yrs. ago when family noted the onset of OCD and cognitive disturbances. [Patient] reportedly had exposure to tick bites while camping in Big Sur. Mother also stated she recalls rash on L leg. Over past few years, patient has been plagued by progressive fatigue, headaches memory disturbances, myalgias which have left him unable to function.” Id. The doctor also memorialized that the MRI was positive for “bilateral demyelinating plaques.” Id. Under the objective physical exam, the doctor recorded that Mr. Hodge was in no acute distress, “appears tired,” and his “speech [is] halting, but appropriate.” Id. For the assessment plan, the author indicated “Possible Lyme Disease.” Id. The author elaborated “although [cerebrospinal fluid] is not suggested of Lyme, given the [positive] IFA and history of tick exposure, and clinical/radiographic findings, will opt to treat for neuroborreliosis [with ceftriaxone] x 2 months and doxycycline x 6 months.” Id.

On December 11, 2009, Mr. Hodge was evaluated by Dr. Mathisen. Exhibit 14.1 at 3. At that time, Mr. Hodge was 24 years old with chronic neuropsychiatric syndrome (depression; obsessive compulsive disorder; changes in cognition). Id. Dr. Mathisen recounted Mr. Hodge’s medical history: possible Lyme disease for 4 to 5 years, tick bites, rash that was treated with short course of antibiotics. Id. On evaluation in neuro clinic, Mr. Hodge was “found to have small demyelination lesions on MRI as well as + Lyme titer (+ ELISA IgG; few bands on WB test).” Id. “Brain PET scan demonstrated areas of ‘cortical hypoperfusion’ consistent with past reports of neurolyme. LP was negative--no pleocytosis; serology negative.” Id. Dr. Mathisen opined that the neuropsychiatric testing demonstrated cognitive deficits that were not compatible with standard psychiatric diagnoses such as schizophrenia or affective disorders. Id. Dr. Mathisen’s assessment states the following:

Neuropsychiatric disorder: [patient’s] symptoms are compatible with chronic neurolyme as described in literature. He has a positive peripheral serology (ELISA) but does not meet CDC criteria by Western Blot. [Patient] and family are aware of this but still strongly wish IV therapy. Multiple sclerosis is the other possibility but is not completely supported by clinical course, MRI and LP results. I believe that a course of

antibiotic therapy is reasonable and plan to repeat tests (MRI; PET scan; neuropsychiatric testing) following completion of therapy. Depending upon [patient's] response, may also give 6 month course of doxycycline after initial rx with ceftriaxone. [Patient] and family member are fully aware of the potential benefits and risks of this course and have decided to go ahead with treatment.

Id.

On December 17, 2009, Mr. Hodge had a follow-up visit with Dr. Dasher as Mr. Hodge was being “currently followed for possible neurolyme with neuropsychiatric [symptoms].” Exhibit 7.1 at 37. This report stated: “some fam [history] GM – [hoarder]. GFA - anxiety + mood swings.” Id. Dr. Dasher’s assessment was “OCD-like” symptoms associated with anxiety and “possible Lyme” disease with neurological symptoms “can’t exclude 1^o cause.” Id. Dr. Dasher recommended a medication, supportive therapy and a return to the clinic in 3-4 weeks. Id.

On December 22, 2009, Mr. Hodge presented to the emergency department at Olive View with a body rash and a week of fevers. Exhibit 7.1 at 3; see also Exhibit 14.1 at 5. The recent antibiotics PICC line was noted. Exhibit 7.1 at 3. The rash resolved within a day. Id. at 68.

When he was evaluated the following day, December 23, 2009, Mr. Hodge underwent visual evoked potential testing. Id. at 27. The results were normal and interpreted as not supporting an MS diagnosis. Id. Dr. Mishra conducted EMG testing, and the study was normal, not supporting a polyneuropathy. Id. at 29-31.

Mr. Hodge was discharged from the hospital on December 23, 2009. Exhibit 7.1 at 68. The author of the discharge report stated that Mr. Hodge had “possible neuro-Lyme.” Id. For Mr. Hodge’s skin rash, the possibilities included a “drug-induced rash secondary to ceftriaxone use and less likely other entities, including a Jarisch-Herxheimer reaction.” Id. Accordingly, ceftriaxone was discontinued and Mr. Hodge was placed on doxycycline. Id.

Dr. Mathisen evaluated Mr. Hodge again on December 31, 2009. His assessment remained “possible Lyme disease” but noted “[d]iagnosis is not proven as CSF serology has been negative.” Id. at 21.⁴⁷

⁴⁷ Some of the handwriting in this note is difficult to read.

(c) Mr. Hodge's Health from 2010 to the Present

The parties dedicated relatively little attention to medical records from 2010 to the present. See Pet'r's Posthear'g Br. at 15-16; Resp't's Posthear'g Br. at 19-21. The undersigned has reviewed the medical records from 2010 onward and determined that they are unlikely to provide information regarding Mr. Hodge's pre-vaccination condition(s) and whether the vaccines caused any sequelae. Nevertheless, a summary of these records is as follows.

Mr. Hodge had follow-up visits with Dr. Mathisen and Dr. Dasher between January 2010 and March 2012. See exhibit 7 and exhibit 12. Via referral from Dr. Mathisen, Mr. Hodge was evaluated by Dr. Wendy Clough on January 11, 2010. Exhibit 13 at 4-7. Dr. Clough's history of present illness begins with Mr. Hodge "develop[ing] severe symptoms starting about 2 years ago, which include psychiatric symptoms including emotional breakdown, physical withdrawal, but also severe myalgias, headaches, fatigue and other complaints such that he has been largely dysfunctional since then." Id. at 5. The history continues:

The patient and his mother recall that the patient had spent a great deal of time visiting in Monterey County near Salinas and also in the Big Sur area because his grandparents were there. At age 17, the patient and the rest of his family had camped out at Big Sur. The patient's mother recalls that there were ticks all over them, their dog, and their belongings at that time. Approximately 2 months after that trip, the patient developed severe muscle aches and fatigue. The patient also may have had some rashes, which his mother believes could have been of the bull's eye type. Six months after the camping trip, the patient suddenly developed OCD and in fact has not really been normal since that time, although it is noted he did have the major breakdown starting 2 years ago.

Exhibit 13 at 5.

Dr. Clough discussed potential causes: "The cause of the problems 2 years ago was unclear. Two aspects of the onset were almost simultaneous in that the patient had developed chronic sinus complaints and had been given amoxicillin for these and appeared to have problems with the amoxicillin such that these symptoms were worsened; however, he had been given a hepatitis B vaccine at

around that time as well. The patient and his mother stated he was angry, agitated, and had hallucinations.” Id. Dr. Clough wrote that Mr. Hodge “was followed at a mental health clinic, but no specific diagnosis other than the OCD was found, and apparently the feeling among his Psychiatry team was that this was not primarily a psychiatric disease.” Id.

Dr. Clough summarized some of Mr. Hodge’s treatment at Olive View, where an MRI found lesions in his brain. However, a neurologist did not consider Mr. Hodge to have multiple sclerosis. “In the meantime, the patient’s mother had found out that other people in the area of Big Sur and also Monterey County, where the patient had been, had contracted Lyme disease, and she became concerned about this.” Id.

Dr. Clough’s summary for Lyme disease indicates that Mr. Hodge “has had some positive test for Lyme disease, although Western Blot at Stony Brook sent at my suggestion is not confirmatory. Because of [a] lack of alternative diagnoses and concern for a central nervous system Lyme disease, the patient was finally started on intravenous ceftriaxone. However, about 10 days into the course, the patient developed significant worsening of his condition with worsening mental symptoms, flu-like feelings, severe pain, chills, aches, and diffuse redness over his upper body, and increased heart rate. The patient was hospitalized. It is still not entirely clear whether he was actually having a reaction to ceftriaxone or whether he is reacting to treatment of the Lyme disease.” Id.

She concurred with Dr. Mathisen’s assessment, stating “most likely [Mr. Hodge] does have Lyme disease.” Id. at 7. Dr. Clough stated that “There appears to be some concerns that the patient could in fact have Lyme disease in the central nervous system and elsewhere since he would have had a high probability for exposure at approximately age 17, but possibly before or after that time as well.” Id. at 7. For a plan, Dr. Clough considered various medications including “perhaps azithromycin with Plaquenil since the immunomodulating properties of these can be helpful.” Id.

In late January 2010, Dr. Mathisen started treating Mr. Hodge with IV penicillin. Exhibit 7.1 at 19. Subsequently, on February 25, 2010, Dr. Mathisen assessed Mr. Hodge as improving, with increased mental sharpness and “better OCD.” Id. at 15.

On May 12, 2010, Mr. Hodge had a normal electroneuromyographic and nerve conduction. Exhibit 12.2 at 245-47. He had a normal EEG study on May 17, 2010, with no evidence of a seizure disorder or brain dysfunction identified. Exhibit 7.1 at 32-33. Mr. Hodge was started on doxycycline along with the IV

penicillin treatment. Id. at 11. The penicillin treatment was discontinued in June 2010. Id. at 10.

An MRI from April 14, 2011 found some lesions in the left frontal lobe had increased and there were two or three new punctate lesions in the frontal gyrus. Exhibit 12.1 at 11. “Differential considerations remain the same but this could be compatible with Lyme disease given patient history.” Id.

An MRI was performed in January of 2012. Exhibit 14.2 at 252-53. There was not much change from the April 2011 MRI. Id. at 253. The interpreting doctor thought the results were most consistent with known history of Lyme disease. Id.

Mr. Hodge began seeing Dr. Kevin Pimstone, a new primary care doctor, in May 2014. Exhibit 32 at 56-58. Dr. Pimstone provided a recitation of Mr. Hodge’s history. Id. at 63. Dr. Pimstone’s impression was neurocognitive decline in addition to OCD symptoms and depression since age 19, possible Lyme disease, abnormal MRI consistent with “possible demyelinating disease versus Lyme disease,” and elevated Epstein-Barr antibody, among others. Id. at 64. Mr. Hodge returned to Dr. Pimstone on numerous occasions and was referred to various specialists throughout 2014 and 2015. See, e.g., id. at 285, 689, 781, 1361, 1481, 1559, 1590, 1643, 2008. A neurologist, Dr. Giesser, evaluated Mr. Hodge on January 20, 2015, as he was experiencing numbness in his hands and feet, heat sensitivity, difficulty thinking, and auditory/visual hallucinations at that time. Id. at 781.

In 2015, Mr. Hodge was evaluated by Dr. James Landen. See exhibit 33. Assessments included psychosis, bipolar disorder, and tardive dyskinesia symptoms. Id. at 1. His reactions to various medications were recounted. See id., passim.

In 2018, Mr. Hodge was taken to the emergency department of West Hills Hospital and treated for “chest pain of unclear etiology.” Exhibit 59.

2. Unavailable Records / Unsuccessful Records Requests

The following recites the unsuccessful records requests from facilities that may have treated Mr. Hodge from 2006 onward.

Records were requested from Noble Community Medical Associates of LA. A verification letter revealed the facility had a flood in early 2017, in which records, including Mr. Hodge’s, were destroyed. Exhibit 64.

A records request was sent to Step Up / Daniel's Place, a mental health support center. The facility indicated they did not have any records indicating Mr. Hodge was enrolled in their mental health services. Exhibit 62.

Despite the existence of some records from Transitional Youth, discussed above, the records department later stated Mr. Hodge was never in one of their programs. See exhibit 82.

In 2018, records were requested from Valley Coordinated Children's Services within the Los Angeles County Department of Mental Health. The records requested were destroyed due to the department's retention policy. Exhibit 72.⁴⁸ For similar reasons, records from West Valley Mental Health were destroyed. Exhibit 81.⁴⁹

3. Testimony

Ms. Elson's recollections of events after the 2006 vaccinations are noted below.

a) Ms. Elson's Affidavits

The following section recites the remainder of Ms. Elson's affidavits. The remainder concerns Mr. Hodge's health from the date of the first hepatitis B vaccination (March 17, 2006) onward.

(1) Affidavit #1

Ms. Elson recalls that on the evening of March 17, 2006, "[Mr. Hodge] became violently ill with chills followed by hot flashes and stabbing pains that felt like electric shocks up his spine, his legs, and his arms." Exhibit 9 at 2. Ms. Elson thought he caught the flu. He improved over the next few days and still felt tired, but his symptoms did not seem too alarming. Id. After the second booster vaccination on April 25, 2006, Mr. Hodge's "health declined rapidly" as he "complained of horrible fatigue, numbness in his arms, and stiffness throughout his body. He was unable to concentrate for any length of time. He left school" Id.

Next, she recalled rushing Mr. Hodge to the ER at Valley Presbyterian Hospital on June 2, 2006, due to complaints of terrible body pain, stiffness, and

⁴⁸ It is possible Mr. Hodge was treated at this facility prior to 2006.

⁴⁹ Some records from West Valley were provided and are discussed above. This implies the West Valley records are incomplete.

numbness throughout his body. “He was in a ‘fog’ where he could not remember things happening around him.” Id. She claims he lost his health insurance because he was deemed to have a pre-existing condition. Subsequently, she recalls he received a brain MRI at Olive View, which revealed an undiagnosed demyelinating condition and evidence of at least five oligoclonal bands. Id. at 3. The suspicion at that time was MS.

(2) Affidavit #2

Regarding the events of 2006 onward, the next affidavit continues:

After the March 2006 shot he shot [sic] it was night and day. It was like he got hit by a bus. He got very very ill within the month after the shot. He deteriorated rapidly. He went to the emergency room within a week. He had severe pain shooting up and down his spine. He was screaming in pain. His eyes were jittery and moving all over the place. That didn’t stop for the next year. He had to drop out of school.

Exhibit 19 at 1. She claims that after “the shot” (it is unclear whether this refers to the first or second hepatitis B vaccination), “he couldn’t do anything. Couldn’t do any of the things he loved. [Mr. Hodge] was wiped clean. Like his brain was scrambled.” Id.

Ms. Elson reported that his health declined rapidly within six months. She alleged: “He didn’t know who he was. He forgot his past. He was urinating and defecating in his pants. He would go days without eating. He dropped to 90 pounds.” She recalled the doctors’ visits that followed, in which Mr. Hodge was scared. “He would tell them his symptoms but then as it progressed he stopped talking to the doctors. I communicated for him. It was too difficult for him.” Id. at 2. She described him as “completely mentally disabled” between 2006 and 2009.

Regarding insurance Ms. Elson stated that Mr. Hodge had MediCal – Medicaid. However, “[t]hey refused to cover MRIs. He was constantly refused medical care. He was denied an MRI numerous times. We requested MRIs in every emergency room we were in and were denied. Easily 12-14 times we asked for MRIs and were told no.” Id.

(3) Affidavit #3

This affidavit makes numerous claims regarding Mr. Hodge's functioning after his 2006 vaccinations. Ms. Elson testified before 2006, Mr. Hodge engaged in some OCD rituals, discussed above. She testified that after the 2006 vaccinations, his OCD rituals consumed his entire life. Exhibit 21 at 1.

She stated Mr. Hodge was on track to get his GED toward the end of 2005 but could not attend school with the rest of his peers and his OCD caused him to fall too far behind to keep up with ordinary classes. Id. at 1. She testified his symptoms and rituals became so severe during the summer of 2006 that he could not attend any classes. Id.

Ms. Elson alleged that after the April vaccine, Mr. Hodge could not form full, coherent sentences and he instead screamed phrases like "I don't even know who I am" and "I can't feel anything." Id. She noted rapid eye fluttering during the summer of 2006. She alleged he could not sleep for days at a time and could not properly use the restroom for multiple years. Id.

"The hallucinations started during the summer of 2006." Id. at 2. She recalled he said angels, demons, and people screamed at him; the hallucinations were sometimes comforting, other times scary, and persisted for years. Id.

Ms. Elson alleged Mr. Hodge "tried to burn down [their] house the summer of 2006—more than once." Id. She wrote that he would turn on the gas stove and put paper and other objects, including his own hand, into the flames. She reportedly feared he would burn the house down.

Ms. Elson stated Mr. Hodge "could not feed himself for several years after the vaccine. He weighed 160 pounds around August of 2006. By 2007 he weighed approximately 90 pounds." Id. She alleged he went days without eating or drinking water, and at other times, "took jars of salt and dumped them on his food." Id.

She alleged he was "afraid to leave the house" but also that "[m]ost days of the week, between 2006 and 2009, he would not come inside the house and [she] had to sleep outside in [her] car watching him." Id.

Ms. Elson alleged that Mr. Hodge lost insurance because of his preexisting OCD, and without insurance, "every facility shooed us away." Id. at 2. After obtaining MediCal-Medicaid, she started taking him to Transitional Youth. He became secretive about his hallucinations. Id. She recalled holistic/nutritional approaches with Pfeiffer, which were to no avail. She next recalls that a volunteer psychiatrist at Daniel's Place (a free mental health services clinic) told them Mr.

Hodge was too much work, so they stopped going there after one visit. Id. at 3. She reported that things “remained pretty constant until about [2013] when the Risperdol [sic] started to work.” Id.⁵⁰

The general theme of this affidavit was that Mr. Hodge had regressed in extreme ways. Ms. Elson alleged he could not eat or drink, comprehend basic sentences, engage in personal hygiene, wear clothing, or properly use the restroom. She alleged the only “activity” he could do was aimlessly biking for miles into the woods or into the middle of the highway. He ceased to do the activities that were normal for him prior to 2006. Additionally, “[h]e can’t remember most of what has happened to him since 2006.” Id.

(4) Affidavit #4

The purpose of the third affidavit was straightforward and responsive to statements made by experts retained by the Secretary. Dr. LaRusso and Dr. Dunn implied that because Mr. Hodge signed consent forms, he had mental capacity. Ms. Elson wrote Affidavit #3 to clarify that “in many cases [she] signed *for* Jeremy” (*emphasis* in original). Exhibit 26 at 1. She continued, noting Mr. Hodge “would not and could not do certain things. . . . [She] would talk for him at the doctors’ offices. [She] would give his history etc. . . . He was in no way capable of handling his own affairs or make deliberate decisions.” Id.

(5) Affidavit #5

In this affidavit, Ms. Elson recounts that “[w]ithin days” of the March 17, 2006 vaccines, Mr. Hodge “starting having headaches, dizziness, shooting pains up and down his back, and numbness in his arms. After a while, he also developed these weird eye movements that he couldn’t control.” Exhibit 71 at 3. She reported he could no longer play basketball.

The two returned to Noble Community Medical Center on April 25, 2006. She wrote that she told the doctor about the problems Mr. Hodge was having. Id. The symptoms got worse after the second shot. She alleged they could not wait for a neurologist appointment, so she took Mr. Hodge to Valley Presbyterian on June 2, 2006. She then defers to the medical records to describe what was experienced before receiving the 2009 MRI.

She also incorporated her prior affidavits into this affidavit. Id. She also provides some amendments:

⁵⁰ A pharmacy record shows Mr. Hodge was prescribed Risperdal as early as 2004. See exhibit 23.

However, there are a couple of corrections. In Exhibit 19, I described the things as if there was only one shot given in March of 2006. Reviewing the records of the visits for March 16, 2006 and April 25, 2006 has helped me to describe what I remember after each of those shots better.

Id. At this point in time, Ms. Elson's recollection was that Mr. Hodge only saw Dr. Nasse a couple of times after the 2006 vaccines, and not before that point. "It is really hard to remember things from so long ago, but getting the records that the Special Master asked us to get has helped." Id. at 4.

Ms. Elson reiterated that Mr. Hodge had bad mood swings, provided incoherent communications, and could not participate in any of the activities he used to enjoy. Id. She likened his condition to dementia.

(6) Affidavit #6

In the final affidavit, Ms. Elson responded to specific questions posed by the undersigned. The following subsection concerns events from the date of first hepatitis B vaccination onward.

A "'Staying Healthy' Assessment" form was completed at Noble Community Clinic on March 17, 2006. Ms. Elson reported that she filled out the form. Exhibit 86 at 12.⁵¹ On the form, she positively indicated that Mr. Hodge "often feel[s] sad, down, or hopeless," and explained this was due to his OCD. Id.

Ms. Elson indicated Mr. Hodge saw Dr. Nasse after the March 17, 2006 vaccination. Id. at 13. Other than OCD and being somewhat depressed, his "mental health was still pretty normal after the first vaccine." Id. Between the two vaccinations, Mr. Hodge "experienced headaches and shooting pains up and down his back, and numbness in his arms." Id.

After the second vaccine, "he couldn't feel his arms, legs, and skin" and "he experienced severe rapid eye movement." Id. She reported the symptoms continued to get worse, that Mr. Hodge began to tire easily and that his mental health deteriorated. Id. at 14. Though she could not recall specifically when the uncontrollable eye movements began, she stated she knows it got really bad after the second vaccine. Id. "[I]t was constant and progressively worse for at least a year." Id. "All the doctors that saw Jeremy saw it after Noble Community Clinic." Id. She also stated he had severe spine and neck pain, and lost sensation in his

⁵¹ The assessment consists of a series of questions to which one completing the assessment answers the question by placing a check in the box "no," "yes," or "skip."

lower legs and arms. Id. at 15. Similarly, she reported he had coordination and balance issues, and experienced sporadic pain for years. Id.

When asked whether Mr. Hodge was seeing a psychiatrist or psychologist during the summer of 2006, Ms. Elson wrote: “I don’t remember. To the best of my knowledge, he was only seeing the people that gave him the Prozac and Zoloft.” Id. at 14. She alleges they were denied MRIs due to not having private insurance. Id. at 15-16.

Ms. Elson recalled that they went to Valley Presbyterian instead of the Noble Clinic in June 2006 because they could not wait for a neurology appointment and she did not trust the people at Noble. Id. at 16. When asked about the medical record indicating Mr. Hodge denied having pain at that visit, she guessed that the notation might be an error. Id. at 17. When asked what the doctor’s recommendations were after discharge, she reported it was to go to a neurologist and get an MRI, and that she remembers subsequently going to “at least four or five times to an ER near [them].” Id. at 18.

Between June 3, 2006 and August 21, 2006, Ms. Elson “think[s]” they were living at her mom’s place in Encino. Id. She stated that during this time, his OCD “was still there, but the focus was on other problems, so OCD wasn’t at forefront of concerns. It seemed like it wasn’t as bad, but it came back with a vengeance later on.” Id.

She recalled making one or two visits to Encino-Tarzana, and that Mr. Hodge had been having abnormal eye movements and dizziness problems in the days leading up to that visit. Id. at 19. She reportedly asked for an MRI but the medical staff could not provide one. Id. at 20. They did not follow instructions to follow up with a private doctor due to an inability to obtain insurance. Id.

However, Mr. Hodge did have insurance through Health Net for their visit to UCLA Medical Center on November 3, 2006. Id. She reported his OCD was “about the same as before” at this visit. Id. She alleged that she “begged for an MRI, but they refused.” Id. at 21. The discharge plan was to follow up with a private doctor or county or community clinic. Ms. Elson could not remember whether they did so or not. Id. She also did not have much recollection of what they did for Thanksgiving in 2006. Id.

When asked what emergency rooms they visited between August 2006 and July 2007, Ms. Elson wrote: “We went to West Valley ER Hospital 6-7 times,

Valley Presbyterian, Encino, UCLA, Northridge Hospital, Ventura County ER, St. Joseph's Hospital Burbank, Pfeiffer Treatment Center outreach." Id. at 23.⁵²

Ms. Elson alleged that it was after the July 10, 2007 visit to West Valley that Mr. Hodge's mental health significantly deteriorated. Id. at 22. "He started to go through psychosis and had crippling fear. He would stay in the corner shaking, believing [the] house was evil." Id. at 23.

On September 9, 2007, Mr. Hodge went to West Hills Hospital. See exhibit 8.5. The record states Mr. Hodge "was recently started on dextrostat for possible ADHD." Id. at 76. Ms. Elson alleged Dr. Nasse prescribed the medication. Exhibit 86 at 24. "He had a bad reaction to it. When he took it, I had to chase Jeremy up the street." Id. She stated Dr. Nasse diagnosed him with possible ADHD but could not remember when. Id.

The affidavit also asked Ms. Elson to recall when she began investigating potential causes for Mr. Hodge's condition(s). She reported she started her research about six months before contacting Mr. Shoemaker. Id. at 26. Additionally, she noted: "Every single doctor after Olive View said that it was a strong possibility that vaccine triggered autoimmune reaction. Even at UCLA I was told that it was a possibility." Id.

b) Ms. Elson's Oral Testimony

Ms. Elson testified that after the first vaccination on March 17, 2006, Mr. Hodge's eyes started fluttering and he complained of spinal pain and itching. Tr. at 149. Ms. Elson did not immediately take Mr. Hodge to the doctor for any of these symptoms because "[the symptoms] didn't seem serious enough [at that time]." Id. Eventually, during an appointment on April 25, 2006, the two allegedly told Dr. Rodriguez about the eyes fluttering, itchiness, shooting pains in the spine. Id. Based on Ms. Elson's observations, Dr. Rodriguez did not seem to think that those symptoms were an issue. Id. Ms. Elson recalled Dr. Rodriguez saying something about a referral but was not actually referred.

Then, "[a]ll hell broke loose" after the second hepatitis vaccine on April 25, 2006. Id. at 150. When asked to clarify what "all hell broke loose" meant, Ms. Elson described the following:

⁵² It seems that West Valley is a mental health treatment center, not an emergency room. See exhibit 11. If there is a West Valley emergency room, records from that facility were not filed.

[Mr. Hodge's] eyes ... were a slight flutter before, went to absolute uncontrollable moving, even while he was sleeping. It drove him insane. Horrible pain all over his body. He was physically completely uncomfortable. And then his skin on his arms and like his upper thighs, he was complaining he couldn't feel them. There was numbness on the surface. Physically, he was weak, he was dizzy. He couldn't do anything. He couldn't play basketball. He couldn't concentrate. His physical symptoms were really bad. . .

[As for the OCD], it literally went through the roof. He spent all day long and never slept and it was ritualistic behavior constantly. His personality completely changed. He went from a really kind, nice, happy-go-lucky person to a very scary person to be around. He turned into the opposite of what he used to be. He also started hallucinating, hearing things, and manic, he just never slept, he paced all the time, very angry.

Id. at 151-52.

Though Ms. Elson provided a detailed account of Mr. Hodge's symptoms and behavioral changes, on cross-examination, she professed to not recalling several details. Id. at 183-188, 193-194.

Ms. Elson testified that after the second vaccination, everybody saw Mr. Hodge's eye movements, and doctors noted that his eyes were jiggling up and down, though she was not certain if they were documented in all his medical records. Id. at 181. The eye movements were mild after the first vaccination but became very intense after the second vaccination. Id. at 182. Ms. Elson stated that after the second vaccination, she had no idea about Mr. Hodge's Lyme disease. Id. at 189.

Ms. Elson recounted that during the summer of 2006, Mr. Hodge's hallucinations started. Id. at 214. Ms. Elson confirmed Mr. Hodge's complaints of "angels, demons, people scream[ing] at him, sometimes voices comfort him, other times scary voices moaned and groaned, telling him what to do." Id. However, according to Ms. Elson, Mr. Hodge sometimes denied hallucinations, depending on whatever cycle he was in. Id. at 215. Mr. Hodge did keep his hallucinations secretive at times. Id. at 222.

In November of 2006 while Mr. Hodge was at UCLA, he was in the emergency room where he complained of skin sensation issues and facial pain. Id. at 188. It was at this time that Mr. Hodge started to experience severe mental health issues. Id.

Ms. Elson stated that they lived at the hospital and emergency room during this entire ordeal, which “felt like life and death.” Id. at 150. She testified she requested an MRI “[e]very time” they went to an emergency room, but was denied until 2009 because they had Medi-Cal / Medicaid. Id. Ms. Elson testified that she regrets taking Mr. Hodge to get his vaccinations because there is “zero doubt” in her mind that the vaccines caused his symptoms, so she has to “live with that guilt every day of [her] life.” Id. at 233.

c) Expert Commentary

(1) Dr. Tornatore’s Testimony

Dr. Tornatore’s testimony built upon Ms. Elson’s statements. He noted that numbness and tingling followed the vaccines and were suggestive of a neurologic vaccine injury. Tr. at 25. Mr. Hodge had not exhibited these symptoms prior to the March 17, 2006 and April 25, 2006 vaccinations. Id. Specifically, Dr. Tornatore testified that within 38 days of the March 17, 2006 vaccination,⁵³ Mr. Hodge’s eyes were jumping around, a condition involving the ocular motor system of the central nervous system, which is different from OCD. Id. These uncontrollable eye movements fit within the time frame for an autoimmune reaction. Id. at 59. Dr. Tornatore characterized the abnormal eye movements as oscillopsia, which is associated with demyelinating conditions. Id. at 63. Dr. Tornatore explained that these eye movements could be intermittent and parents may not have recognized the importance of them. Id. at 68-69.

Mr. Hodge received a second vaccination on April 25, 2006,⁵⁴ approximately 40 days after receipt of the first vaccination. Id. at 58. Dr.

⁵³ On the same day of the March 17, 2006 vaccination, Mr. Hodge complained of “pressure over his face that was thought to be sinus in origin and a productive cough” and was “prescribed [A]moxicillin or Amoxil.” Tr. at 58.

⁵⁴ At the April 25, 2006 visit, it was noted that Mr. Hodge was treated by a psychiatrist and he complained of “getting uncontrollable eye movements, neck pain, and itching, and . . . was on Zoloft.” Tr. at 58, 240-41. Dr. Tornatore explained that while the symptoms of neck pain could be consistent with acute Lyme disease since people, who are recently infected, will get meningitis, this theory does not apply in Mr. Hodge’s case because he is “presumably many .

Tornatore testified that according to Ms. Elson, the abnormal eye movements persisted for about a year once they started. Id. at 70. After the second vaccine, the symptoms were “constant and progressively worse for a year . . . nonstop movement up and down.” Id.; Exhibit 86 at 14. Dr. Tornatore contended that by the second vaccination, it was established that Mr. Hodge suffered a demyelinating event. Tr. at 240. Dr. Tornatore conceded that the MRIs from 2009 did not show signs of a demyelinating event in March or April of 2006. Id. at 243. Mr. Hodge’s constitutional symptoms could also be attributed to an immune-mediated event and the eye findings point to the central nervous system. Id. at 241. Dr. Tornatore stated that nothing in the medical records shows that Mr. Hodge’s doctors considered the symptoms Mr. Hodge was describing as being a demyelinating event. Id. at 244. Dr. Tornatore acknowledged Mr. Hodge’s case is a complicated one. Id.

Dr. Tornatore stated that one cannot assume Mr. Hodge’s MRI at the time of vaccination would have been normal. Id. at 62. Despite Mr. Hodge’s neurologic symptoms after the first vaccination, he still received a second vaccination, which Dr. Tornatore stated “[i]n retrospect, it’s a little easy” [to] “fault the practitioner for not recognizing something like that.”⁵⁵ Id. at 26. Mr. Hodge had some inflammation already in the nervous system prior to the vaccinations, so he was prone to neurologic symptoms. Id. at 33. Dr. Tornatore postulated the vaccines caused autoimmune demyelination, which aggravated the neuroborreliosis (which he characterized as an underlying autoimmune inflammatory condition). Id. at 26-27. In his opinion, the reported eye fluttering was a neurological manifestation of vaccine injury. Id. at 27.

Dr. Tornatore pointed out that in April 2006, Mr. Hodge was referred to neurology for his uncontrollable eye movements and not a psychiatrist, indicating that it was a neurological issue and not a psychogenic matter. Id. at 77, 460-61. Dr. Tornatore explained that “uncontrollable eye movements where the eyes are moving around [are] always neurologic.” Id. at 80. Dr. Tornatore thinks all problems, including chemical imbalance, are ultimately structural. Id. at 82-84.

Dr. Tornatore did not agree with Dr. Venkatesan’s assessment that Mr. Hodge experienced a Jarisch-Herxheimer reaction because 1) Mr. Hodge was

. . . years out from [his infection.]” Id. at 241. Therefore, Dr. Tornatore attributes the “neck pain, the arthralgias, and the muscle aches and fatigue” to vaccination. Id. at 242.

⁵⁵ Dr. Tornatore stated that under these circumstances, National MS Society would not recommend vaccinating. Tr. at 26.

treated with Amoxicillin, which is “not a drug of choice for Lyme disease because it has relatively not great tissue penetration into the nervous system,” 2) “Mr. Hodge had been treated with Amoxicillin on April 19, 20[0]4 . . . and had no [adverse response] at all to Amoxicillin” See Exhibit 3.1 at 3. 3) Amoxicillin, in order to invoke Jarisch-Herxheimer, busts open the spirochete and “given that Amoxicillin really doesn’t have great tissue concentration levels that rise, it’s hard to imagine that . . . [would] cause a Jarisch-Herxheimer reaction” and 4) Mr. Hodge “didn’t have any constitutional symptoms of a Jarisch-Herxheimer reaction . . . didn’t have fever, rash, headache, any of these other things that would suggest that there is a brisk immune response due to the splitting open of the spirochete.” Id. at 35-36. Dr. Tornatore acknowledged that either the vaccine or Amoxicillin could potentially cause inflammation of the nervous system but ruled out Amoxicillin as the likely cause based on his foregoing reasons. Id. at 66-67.

In assessing Mr. Hodge’s clinical picture, Dr. Tornatore assumes Mr. Hodge’s OCD was a manifestation of neurolyme.⁵⁶ Id. at 34, 39. This assumption, coupled with the 2009 MRI and spinal fluid results, forms the foundation of his significant aggravation theory. Id. at 34. But for exposure to Lyme disease via the tick bite, Dr. Tornatore opined, Mr. Hodge would not have OCD. Id. at 42.

On June 2, 2006, Mr. Hodge went to the emergency room at the Valley Presbyterian Hospital. Tr. at 77; Exhibit 6.1 at 3, 6-10. During this visit, horizontal or vertical nystagmus⁵⁷ were not documented. Id. Dr. Tornatore stated that nystagmus can be evidence that there is an ocular motor issue or that there’s a brainstem issue. Tr. at 77. The CT scan of the head was normal, but no MRI was ordered. Id. at 78. In Dr. Tornatore’s opinion, the fact that the CT scan was normal does not detract from the fact that Mr. Hodge had these neurologic symptoms. Id. He explained that a CT scan “rules out really bad things, but it doesn’t rule out more subtle things . . . [and does not reveal] an active inflammatory process.” Id. at 312.

⁵⁶ Dr. Tornatore testified that it is uncertain where Mr. Hodge went on his camping trip and contracted Lyme disease, but sometime after this trip, he developed neurolyme, possibly 2005 or earlier. Tr. at 39. Dr. Tornatore acknowledged that “when [] the actual infection happen[ed] . . . is very difficult to discern from the records.” Id. at 34. Nonetheless, he maintained confidence that neuroborreliosis preceded the vaccinations. Id. at 34-36. The Court accepted this account.

⁵⁷ Dr. Tornatore explained that nystagmus is when a person “move[s] [his or her] eyes to the extreme . . . right, extreme left, extreme altitude or latitude, that the eyes will jiggle a little bit.” Tr. at 77.

Dr. Tornatore testified that the June 2, 2006 medical records “associate arthralgias and myalgias with the hepatitis vaccinations [, so] they are invoking some inflammatory event, not demyelinating [event].” Id. at 245. Dr. Tornatore assumed that “status post-hepatitis vaccination” meant those symptoms were “reported as occurring after the vaccine;” he could not state with certainty that they were the result of the hepatitis B vaccine. Id. The treating physician at this visit recommended Mr. Hodge to attend a follow-up appointment. Id. at 84.

Dr. Tornatore discussed that possibly Mr. Hodge was not getting proper treatment for his neurologic symptoms. Id. at 54. Mr. Hodge went to an emergency room repeatedly in hopes of getting treated for his symptoms, and while physicians suggested him to seek care from a neurologist, he was not actually referred to a neurologist. Id. at 54-56. Dr. Tornatore explained that the process of seeing a specialist, such as a neurologist, is a hard process. Id. at 56.

In a subsequent visit to the emergency room on August 23, 2006 at Encino-Tarzana Regional Medical Center, Mr. Hodge presented with dizziness and generalized weakness, and Dr. Tornatore testified that the “dizziness could be due to an eye movement problem” but admitted that he did not actually know what the cause of the dizziness would be. Id. at 85. Medical records from this visit had no specific complaints about eye problems and no indication of a concern for oscillopsia. Id. at 86. The records show that the extraocular muscles were intact, which means that they are able to move appropriately. Id. Mr. Hodge’s major symptom was a sensory disturbance. Id.

During the August 23, 2006 visit, Mr. Hodge presented with new neurologic symptoms, namely paresthesias, tingling, and difficulty of feeling skin – these were symptoms that he did not have previously. Id. at 314. Dr. Tornatore did not feel confident to express whether or not Mr. Hodge’s OCD was actually worse during this period. Id. Dr. Tornatore reasoned that the vaccination caused a demyelinating inflammatory event that triggered Mr. Hodge’s eye issues and the sensory issues. Id. at 317. Dr. Tornatore explained that Mr. Hodge could have inflammation that is persistent, starting in one area and then moving to another area. Id. at 333. He further emphasized that Mr. Hodge’s eye issues and sensory issues were not present prior to the vaccinations and were not part of his symptom complex of the OCD. Id.

While at UCLA in November 2006, Mr. Hodge had decreased sensation of skin, which according to Dr. Tornatore, speaks to a neurologic problem along with the eye movement issues. Id. at 316.

(2) Dr. Venkatesan's Testimony

According to Dr. Venkatesan, based on his review of the evidence and medical records, there was no evidence of a demyelinating event following the 2006 vaccinations. Tr. at 370. He described that at Mr. Hodge's second vaccination appointment on April 25, 2006, there were complaints of itchiness, neck pain, facial pressure, and uncontrolled eye movements. Id. From then on, "those eye movements worsened over the subsequent month, such that they became constant and very noticeable and even debilitating by the time of the June 2nd visit to the emergency room where there is documentation that there were complaints of eye movement and balance abnormalities along with some arthralgias and myalgias." Id. at 371. Dr. Venkatesan disagreed with Dr. Tornatore's assessment that the onset of a demyelinating event would lead to aggravation of neuroborreliosis because there is nothing in medical literature that supports that theory. Id. at 381. Dr. Venkatesan also stated, hypothetically, if one were to conclude that there were demyelination that resulted in a nervous system problem that then resulted in the eye movement abnormalities, then there would be "appropriate timing [but] that's a big stretch." Id. at 386.

Dr. Venkatesan discussed the Jarisch-Herxheimer reaction was a possible explanation for some of Mr. Hodge's symptoms after the vaccine. Id. at 379. He explained that Jarisch-Herxheimer reaction "was originally described in the setting of treatment of syphilis where when the organism is killed . . . the thought is that substances are released that then provoke an inflammatory response that results in a transient worsening of symptoms . . . [and] since those original descriptions in neurosyphilis, there have been other situations in which the thought is that this could occur and it's possible that this occurs in the setting of Lyme disease . . . [and] [i]n fact, it's quite probable that it does." Id. at 379-80.

Dr. Venkatesan pointed out that Mr. Hodge was treated with Amoxicillin, an antibiotic. Id. at 180. He reasoned that the Amoxicillin might have gone into the central nervous system and potentially killed some of the spirochete, triggering the Jarisch-Herxheimer reaction. Id. The fact that Mr. Hodge was treated with Amoxicillin while receiving the March 2006 vaccinations seems to be, according to Dr. Venkatesan, the likely explanation for Mr. Hodge's symptoms in April 2006.⁵⁸ Id. Based on the review of the records, Dr. Venkatesan did not think Mr. Hodge's symptoms in April 2006 were severe. Id. at 381.

⁵⁸ Dr. Venkatesan did not know how long Mr. Hodge was treated with Amoxicillin but he thought it was unlikely that he was treated for months and then suddenly he would have

When asked about Mr. Hodge's referral to a neurologist for uncontrolled eye movements, Dr. Venkatesan stated that "the recommendation to see a neurologist or even a referral doesn't necessarily mean that there is a neurologic problem." Id. at 392. Dr. Venkatesan further noted that "oscillopsia is a subjective complaint by the patient that things in visual space are essentially jiggling around . . . [s]o that can be a neurologic symptom, but it can also be a psychiatric symptom." Id. at 394. However, Dr. Venkatesan also admitted that he did not have "enough evidence to conclude that [the uncontrolled eye movements] are neurologic and that there are multiple other possibilities." Id. at 433.

Dr. Venkatesan confirmed that the June 2, 2006 medical records had documentation of an extraocular movement exam that did not reveal any nystagmus. Id. at 371. Dr. Venkatesan acknowledged that there is documentation that Mr. Hodge suffered from either problematic eye movements or vision, or both. Id. Dr. Venkatesan stated there is no nothing in the medical records that the eye movements are "definitively attributable to neurological problems." Id. Dr. Venkatesan was uncertain whether Mr. Hodge's uncontrolled eye movements could be characterized as "oscillopsia" because the description is "uncontrolled eye movements." Id. at 372. He did not know whether Mr. Hodge, in fact, experienced the "sensation of bouncing around vision." Id.

At the Valley Presbyterian Hospital in June 2006, Mr. Hodge reported headaches, which according to Dr. Venkatesan, can have lots of causes, "so there are a number of things that could be going on that don't necessarily point to a specific process within the central nervous system." Id. at 434. Dr. Venkatesan agreed with Dr. Tornatore that a CT scan would not show an inflammatory process. Id. Dr. Venkatesan did not know whether an MRI on June 2, 2006 would have shown damage to corpus callosum.⁵⁹ Id. at 435.

In August 2016, Mr. Hodge complained of paresthesias, which according to Dr. Venkatesan, may be neurologic in origin, but there is no documentation that the sensory exam was abnormal. Id. at 375.

Dr. Venkatesan stated the gap in the medical records between Mr. Hodge's time at UCLA and the summer of 2007 was problematic because there was no way

symptoms in June 2006. Tr. at 447. For this reason, if there is any connection with Amoxicillin and his symptoms, "it would be to the presentation in April [2006]." Id.

⁵⁹ At the time of the June 2, 2006 appointment, Dr. Venkatesan could not state, with certainty, that Mr. Hodge was suffering from Lyme disease because he did not find information in the record to support that. Tr. at 435. However, the Court found evidence to support a finding that Mr. Hodge was suffering from Lyme disease before September 28, 2004.

of knowing what happened during that time frame. Id. at 378. While Dr. Venkatesan acknowledged Ms. Elson's account of Mr. Hodge's uncontrolled, debilitating eye movements, he did not see any objective documentation of Ms. Elson's descriptions. Id.

V. Standards for Adjudication

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

Medical records generally warrant consideration as trustworthy evidence. Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, because medical records are not always complete and accurate regarding a patient's condition(s), it may be appropriate for a special master to credit a petitioner's lay testimony to fill in gaps. Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378 (Fed. Cir. 2021). Nonetheless, special masters are expected to consider the record as a whole and determine how the evidence preponderates. See Britt v. Sec'y of Health & Hum. Servs., No. 17-1352V, 2021 WL 4282596, at *1-5 (Fed. Cl. Spec. Mstr. Aug. 27, 2021) (discussing the creation of and standards for evaluating medical records). Furthermore, special masters may assess the credibility of an individual offering testimony. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009).

As confirmed in W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013), the elements of an off-Table significant aggravation case were stated in Loving. There, the Court blended the test from Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1279 (Fed. Cir. 2005), which defines off-

Table causation cases, with a test from Whitcotton v. Sec'y of Health & Hum. Servs., 81 F.3d 1099, 1107 (Fed. Cir. 1996), which concerns on-Table significant aggravation cases. The resulting test has six components. These are:

(1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving ex rel. Loving v. Sec'y of Dep't of Health & Hum. Servs., 86 Fed. Cl. 135, 144 (2009).

VI. Analysis

A. Explanation of petitioner's theory and how Dr. Tornatore's opinion fits into legal elements

Dr. Tornatore's complex opinion can be divided into a series of steps. First, Dr. Tornatore asserted that years before the vaccinations, Mr. Hodge contracted *B. Burgdorferi*. Pet'r's Posthear'g Br. at 28; Tr. at 22-23. This opinion was derived from Ms. Elson's testimony that Mr. Hodge was bitten by a tick and developed a bull's-eye rash at around the age 14 or 15 (in 2003). Pet'r's Posthear'g Br. at 27. Dr. Tornatore also relied on Dr. Mathisen's assessment in reaching this conclusion. Petitioner also points to the May 19, 2009 MRI and the spinal tap results as support that Mr. Hodge suffered from neuroborreliosis. Pet'r's Posthear'g Br. at 27-28.

From a starting point that Mr. Hodge suffered from Lyme disease years before the vaccination, Dr. Tornatore made additional assumptions about Mr. Hodge's condition. In Dr. Tornatore's version of events, the spirochete took up residence in Mr. Hodge's nervous system and caused persistent inflammation as the immune system attempted to eradicate the spirochete. Then, the persistent infection or immune activation resulting from the infection manifested as OCD. Pet'r's Posthear'g Br. at 28-29; Tr. at 22-23. Dr. Tornatore testified that the first evidence of neuroborreliosis was Mr. Hodge's initial presentation of OCD. Id.

Petitioner further maintains that Mr. Hodge's Lyme-induced OCD was relatively mild. Pet'r's Posthear'g Br. at 30.

These assertions and assumptions about Mr. Hodge's health before the vaccination are the foundation for the assessment of Loving prong 1, which concerns Mr. Hodge's pre-vaccination health. In Loving prong 3, Mr. Hodge's pre-vaccination health is compared to his current condition.

Loving prong 4 is the first step in evaluating whether Ms. Elson met her burden of proof to establish that the hepatitis B vaccine caused the aggravation of Mr. Hodge's health. Dr. Tornatore opines that the hepatitis B vaccines can aggravate (or cause) demyelination. Dr. Tornatore proposes molecular mimicry as the mechanism. Pet'r's Posthear'g Br. at 48, 52-57.

Dr. Tornatore also opines that Mr. Hodge experienced an aggravation of his underlying Lyme-induced OCD because of the hepatitis B vaccine. The bountiful evidence surrounding that topic is evaluated as part of Loving prong 5. Loving prong 6 briefly addresses whether the timing fits.

Finally, apart from the Loving analysis, there is a separate section regarding the contribution of the conditions that affected Mr. Hodge before the vaccination, Lyme disease and OCD. As discussed in section VI.G. below, this part is actually unnecessary to the decision but is evaluated for sake of completeness.

B. Loving Prong 1

The first Loving prong requires the special master to assess "the person's condition prior to administration of the vaccine." 86 Fed. Cl. at 144. While this topic may be straightforward in some cases, Mr. Hodge's health before the vaccination is difficult to evaluate. The Court has made two key findings: that Mr. Hodge displayed symptoms of OCD no later than September 28, 2004 and that Mr. Hodge's "tick exposures and subsequent Lyme disease predated his OCD symptoms." Second Opinion and Order, 164 Fed. Cl. 633, 649 (2023).

These findings do not resolve all questions of fact regarding Mr. Hodge's pre-vaccination health. At least three questions remain open. First, did the Lyme disease, which pre-dated Mr. Hodge's OCD, cause Mr. Hodge's OCD? This question is taken up below in section VI.B.1. The remaining two questions, which are how severe (or mild) was Mr. Hodge's pre-existing Lyme disease and how mild (or severe) was Mr. Hodge's pre-existing OCD, are discussed in section VI.B.2. below.

1. Can Lyme disease cause OCD?

Although the Court found Mr. Hodge's Lyme disease preceded his OCD, this sequence of events does not necessarily mean that the Lyme disease caused his OCD. Thus, whether Mr. Hodge's Lyme disease caused or induced his OCD was not resolved by the Court. Dr. Tornatore opined that Mr. Hodge suffered from Lyme disease and subsequent neuroborreliosis, which caused him to develop OCD. Tr. at 269-72; Exhibit 29 at 8. The Secretary argues Ms. Elson has not established (1) that neuroborreliosis can generally cause OCD or (2) that neuroborreliosis did cause Mr. Hodge's OCD. Resp't's Posthear'g Br. at 36-43.

a) *Petitioner's Position*

Dr. Tornatore opines that Mr. Hodge contracted the Lyme bacterium prior to the OCD diagnosis. Pet'r's Posthear'g Br. at 28; Tr. at 22. After contracting Lyme, in Dr. Tornatore's view, Mr. Hodge's OCD was the first evidence of central nervous system problems caused by Lyme disease / neuroborreliosis. Pet'r's Posthear'g Br. at 29; Tr. at 21-24. In other words, Dr. Tornatore argues Mr. Hodge "developed OCD because of untreated Lyme disease." Tr at 101.

After the Lyme bacterium infects someone, the spirochete can get into some patient's brain. With neuroborreliosis, "there is a persistency of the spirochete in the brain and, as such, the immune system is trying to clear the spirochete. And so there's ongoing inflammation[.]" Tr. at 18-19. According to Dr. Tornatore, it would take time "to develop this kind of inflammation in the brain after the spirochete has taken up residence in the nervous system." Tr. at 23.

Dr. Tornatore relies in part on the Fallon article, in which the authors question "[w]hether the late-stage symptoms of Lyme disease are due to persistent infection or to a postinfectious immune activation." Exhibit E, tab 1 at 1573 (Fallon).⁶⁰ As such, regardless of the mechanisms, Ms. Elson raises this article for support that Lyme disease is a neuropsychiatric illness. Pet'r's Posthear'g Br. at 28-29. Dr. Tornatore testified that with neuroborreliosis, the symptoms "manifest in many different ways. Patients may have cognitive issues, they may have cranial nerve issues." Tr. at 18.

When asked about the best evidence that neurolyme can manifest or cause OCD, Dr. Tornatore referenced the Fallon article, stating it "specifically states that." Tr. at 45. Dr. Tornatore quoted a portion, stating "A broad range of psychiatric reactions have been associated with Lyme disease, including paranoia,

⁶⁰ Bibliographic information for the articles cited in this decision is found in the appendix.

... and obsessive-compulsive disorder.” Tr. at 46 (quoting Exhibit E, tab 1 at 1571 (Fallon)).

Elaborating on the significance of the MRI findings, Dr. Tornatore testified that the changes in the corpus callosum seen in the MRI fits the OCD pattern in the literature. Pet’r’s Posthear’g Br. at 30; Tr. at 62; Exhibit 29 at 9-10. Referencing the Saito article, Dr. Tornatore opined “the whole point of this paper” “is that here we have abnormalities in the corpus callosum that can cause OCD.” Tr. at 122. Despite some different findings, Dr. Tornatore took the Li article to have the same conclusion. Tr. 127-34. Petitioner’s brief explains the Saito and Li articles as follows. The Saito paper “observ[es] abnormal white matter [fractional anisotropy] in the [corpus callosum] rostrum of the patients with OCD.” Pet’r’s Posthear’g Br. at 49 n.12, Exhibit 45 at 541 (Saito). The Li paper demonstrates “OCD is associated with axonal microstructural abnormalities within the white matter[.]” Pet’r’s Posthear’g Br. at 49 n.12, Exhibit 46 at 216 (Li). Furthermore, OCD is significantly more common in individuals with demyelinating disorders – the Foroughipour paper showed that 16.1% of multiple sclerosis patients have OCD, compared to 1-3% of the general population. Exhibit 39 at 22, 25 (Foroughipour). Dr. Tornatore buttresses his position with the Hildenbrand article, which states “The MR imaging white matter appearance of successfully treated [Lyme Neuroborreliosis] and multiple sclerosis display sufficient similarity to suggest a common autoimmune pathogenesis for both.” Exhibit 42 at 1079 (Hildenbrand). For all these reasons, Dr. Tornatore maintains that Lyme disease can lead to OCD.

In addition, Dr. Tornatore further contends that Mr. Hodge’s Lyme disease caused his OCD. In Dr. Tornatore’s view, the first sign of central nervous system involvement from neuroborreliosis is Mr. Hodge’s OCD. Tr. at 23. He bases this opinion on Mr. Hodge’s MRI and spinal fluid records, which shows that Mr. Hodge “clearly [has] inflammatory disease of the nervous system.” Tr. at 24. He further testified Mr. Hodge had neurological symptoms of OCD, followed by numbness, tingling and eye movements. Tr. at 24, 40.

b) Respondent’s Position

The Secretary argues the evidence does not establish that neuroborreliosis can cause OCD or did so in Mr. Hodge. Resp’t’s Posthear’g Br. at 36-43. In other words, the Secretary argues Ms. Elson has not proven that “Lyme-induced OCD” exists. *Id.* at 63. Similarly, Dr. Venkatesan opines it is unclear whether neurolyme

disease can cause OCD and that there is no supportive evidence in this case to suggest neurolyme caused Mr. Hodge's OCD. Tr. at 352.⁶¹

The Secretary questions the general proposition that Lyme disease can cause OCD. The Secretary further disputes Dr. Tornatore's reliance on the Saito and Li medical articles. Both articles examine brain abnormalities in patients with OCD using diffusion-tensor imaging ("DTI"). The Secretary argues Dr. Tornatore "was applying a very broad view of the findings of these papers . . . while ignoring limitations . . . and the contradictory findings." Resp't's Posthear'g Br. at 38. Furthermore, he argues the Saito and Li papers have relevant opposite findings while noting Dr. Tornatore argued the discrepancy is not relevant. Specifically, the Li article found that the fractional anisotropy ("FA") was significantly increased "in the genu and body of corpus callosum and white matter of right superior frontal gyrus and corpus callosum; no areas of significantly decreased FA were found." Exhibit 46 at 216 (Li). The Secretary contrasts this finding with the results of the Saito article, namely, that "[a] significant reduction in FA was observed in the rostrum of the [corpus callosum] in patients with OCD compared with the rostral FA in the control subjects." Exhibit 45 at 536 (Saito). He argues these incongruous findings are significant and undermine Dr. Tornatore's position. Additionally, the Secretary relies on Dr. Venkatesan to dispute Dr. Tornatore's opinion. See Resp't's Posthear'g Br. at 39-43. Dr. Venkatesan notes that the contrary findings in the Saito and Li papers regarding FA reveals greater limitations and issues with attempting to correlate anatomical anomalies with OCD. Tr. at 358.

The Secretary further questioned the utility of the Saito and Li articles by referencing the Koch et al. article, which notes "DTI studies in OCD patients are still rather heterogenous . . . Whether the alterations in structural connectivity are directly linked to . . . alterations in functional activation or connectivity in corresponding or anatomically connected regions remains, however, to be clarified." Exhibit E, tab 6, at 32 (Koch). The Secretary further quotes limitations from Koch et al. to undermine Dr. Tornatore's reliance on the 2009 MRI. Koch et al. concluded: "The question regarding the exact nature of white matter alterations in OCD remains to be clarified and has to be investigated by additional methods and multi-parameter studies which should also help to reduce data heterogeneity." Id.; Resp't's Posthear'g Br. at 40.

⁶¹ The Secretary challenged the version of events in which Mr. Hodge's Lyme disease preceded his OCD. Resp't's Posthear'g Br. at 36-37. However, this challenge is not viable after the Court's finding that Mr. Hodge had Lyme disease before he began to manifest OCD, which was no later than September 28, 2004.

The Secretary critiques Dr. Tornatore's description of OCD as a neurologic condition as opposed to a psychiatric condition and his reliance on the Saito and Li papers which seem to underpin his opinion. Resp't's Posthear'g Br. at 40; Tr. at 281. The Secretary also undermines Dr. Tornatore's reliance on the Fallon paper, which Dr. Tornatore raised as his "best evidence" showing that neuroborreliosis can manifest as OCD. Resp't's Posthear'g Br. at 41; Tr. at 45. He points to several limitations. First, the section of the paper discussing psychiatric manifestations of Lyme disease "focused on one case report involving a college student who was found to have Lyme disease that may have triggered her panic disorder and OCD." Resp't's Posthear'g Br. at 41; see Exhibit E, tab 1, at 1575 (Fallon). The Secretary also notes the authors listed no family history of psychiatric disorders to bolster their opinion of Lyme involvement; he contrasts the case report, stating "Mr. Hodge had a family history of psychiatric disorders," calling into question the applicability of the case report here. Resp't's Posthear'g Br. at 41. Additionally, the Fallon paper acknowledges the association between Lyme and OCD is still being investigated. Id.; Exhibit E, tab 1, at 1571 (Fallon).

The Secretary also quotes portions of Dr. Tornatore's testimony, in which he makes broad statements that tend to undermine his credibility on this issue. Dr. Tornatore opined "it is not unreasonable to think that Lyme disease could cause really any neuropsychiatric manifestation, depression, anxiety, obsessive-compulsive disorder." Tr. at 286. Defending the Fallon, Saito, and Li papers, he stated: "I would say that these articles are good enough, that we've learned what we need to learn, that Lyme can do anything. And it may be rare, but it can do anything." Tr. at 287.

Dr. Venkatesan disagrees that those articles are sufficient evidence to support Dr. Tornatore's theory. Dr. Venkatesan recognizes that the nature of white matter alterations in OCD remains to be clarified, as there is a lot of heterogeneity in the data. Tr. at 362-63; see also Exhibit E, tab 7 at 4 (Milad)⁶²; Exhibit E, tab 8 at 381 (Beucke). This suggests there may not be one discrete neuroanatomic basis for OCD.

In addition to the arguments summarized above contesting whether Lyme disease can cause OCD, the Secretary has raised specific issues as to whether Mr. Hodge's Lyme disease caused his OCD. Specifically, the Secretary disputes Dr. Tornatore's reliance on the 2009 MRI to show Lyme disease caused Mr. Hodge's OCD. The Secretary argues "Dr. Tornatore conceded that he cannot tell when the lesions in Mr. Hodge's brain that were seen on the 2009 MRI developed or say

⁶² The Secretary submitted this article in manuscript form. Therefore, the page cites are to the pdf version, rather than the version that appears in printed journals.

with any certainty that the lesions were present in or prior to March or April 2006. Tr. at 243, 245.” Resp’t’s Posthear’g Br. at 38. The Secretary notes the Saito paper discussed abnormalities in the orbitofrontal region of the brain, but Mr. Hodge’s MRI showed changes in the septal region. Id.; Exhibit 7 at 65; see also Tr. at 120-21.

2. Assessment

a) Mr. Hodge had Lyme disease before he developed OCD.

The Court has found that Mr. Hodge’s OCD was manifest by September 28, 2004. The Court has also found that his Lyme disease predated his OCD symptoms. Thus, this chronology matches what Dr. Tornatore has espoused. However, proximate temporal association alone does not establish causation in fact. See Grant v. Sec’y of Health & Hum. Servs., 956 F.2d 1144, 1148 (1992); see also Tr. at 412 (Dr. Venkatesan opining “the fact that you have coexisting Lyme and OCD symptoms, it doesn’t imply a causative aspect”).

b) Ms. Elson has shown that Lyme disease caused Mr. Hodge’s OCD

In the Vaccine Program, the process for determining whether a vaccine caused a harmful consequence has sometimes involved assessing two questions: 1) Can the vaccine cause the injury? and 2) Did the vaccine cause the injury? See Pafford v. Sec’y of Health & Hum. Servs., No. 01-0165V, 2004 WL 1717359 (Fed. Cl. Spec. Mstr. July 16, 2004), mot. for rev. denied, 64 Fed. Cl. 19, 24-25 (2005), aff’d, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (recognizing this test as compatible with the Althen test). These two questions correspond to “general causation” and “specific causation.” Pafford, 451 F.3d at 1355-56. Here, despite the weakness in Ms. Elson’s evidence about general causation, her evidence on specific causation meets her burden to present a persuasive case. The analysis begins by explaining the deficiencies regarding Ms. Elson’s evidence on the general question before continuing with an explanation of the evidence on specific causation.

First, Dr. Tornatore is not an expert on Lyme disease. Dr. Tornatore did publish one article regarding the detection of *B. burgdorferi* in 1991, but otherwise has focused his career on multiple sclerosis. See Exhibit 84 (Dr. Tornatore’s CV). As explained more extensively in section III above, Dr. Venkatesan possesses superior credentials in the field of Lyme disease. Dr. Venkatesan works at the Johns Hopkins Lyme Research Center and has been invited to speak about Lyme disease. Exhibit L at 1; Tr. at 339, 401.

Second, when discussing the topic of whether Lyme disease can cause OCD, Dr. Tornatore's demeanor was poor, reducing his credibility on this point. See Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1325-26 (2010) (permitting special masters to make determinations as to the reliability of evidence presented and the credibility of testifying experts).

Third, although Dr. Tornatore identified Fallon article as the best evidence supporting his opinion that Lyme disease can cause OCD (Tr. at 45), the Fallon article is unpersuasive in several respects. The Fallon article discussing Lyme disease is old, published in 1994. Exhibit E, tab 1 (Fallon). The paper's discussion of OCD as a consequence of Lyme disease focused on a single case report. Id. at 1575-76. There, an 18-year-old college freshman "suddenly developed severe and sustained anxiety, depersonalization, and panic attacks associated with insomnia and appetite loss." Id. at 1575. Medical personnel at her college suspected that "these symptoms represented an adjustment reaction to being away from home." Id. Two weeks later at home, she tested positive for *B. burgdorferi*. Id. She then recalled that several months earlier, she had a "large annular rash" that was followed by "moderate headaches and uncharacteristic fatigue." Id. One year later, the subject of the case report "developed a return of anxiety with panic attacks and agoraphobia. In addition, she developed rare déjà vu episodes, repetitive musical hallucinations, and intrusive obsessional thoughts and images." Id. at 1576. Based upon this chronology and other information, the authors stated that "Lyme disease may have triggered these symptoms [referring to the panic disorder and obsessive-compulsive disorder]." Id.

In general, case reports provide little, if any, information helpful to determining causation because they present only a temporal sequence of events in which an exposure preceded an adverse health event. See K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July 7, 2016) (discussing appellate precedent on case reports).

Whether the members of the relevant field support or reject Fallon's contention that Lyme disease can cause psychiatric problems, such as OCD, is not clear. One article did cite Fallon and three other articles to support the assertion that "Neuropsychiatric manifestations occur in about 15% of the [individuals affected with Lyme disease]." Exhibit 40 at 149 (Miklossy); see also Tr. at 413. On the other hand, another article's list of symptoms of Lyme disease does not include OCD. See Exhibit 43 (Ramesh); see also Tr. at 287.

In the context of explaining why instances of Lyme disease being associated with OCD appear rarely, Dr. Tornatore stated "there's not a lot of interest in people saying, well, how many people with Lyme disease have OCD. It's an old disorder.

And so there's not a lot of interest in trying to look at that kind of phenomenology." Tr. at 286. Dr. Tornatore's demeanor for this response suggests that his answer lacks credibility. See Moberly, 592 F.3d 1315. Moreover, as the Secretary argued, the existence of a research center at Johns Hopkins University devoted to Lyme disease contradicts Dr. Tornatore's statement. See Resp't's Posthear'g Br. at 42.⁶³

Fourth, Dr. Tornatore's reliance on articles reporting results of diffusion tensor imaging was also unpersuasive. Preliminarily, Dr. Tornatore's demeanor was poor on this point as well. Part of Dr. Tornatore's trouble might be that he seemed unprepared (or at least less prepared than Dr. Venkatesan) to discuss these articles. Although Dr. Tornatore cited the Saito and Li papers in his January 22, 2017 expert report and Ms. Elson cited them in her brief before the hearing, Exhibit 29, Pet'r's Prehear'g Mem. at 33, Ms. Elson elicited no testimony from Dr. Tornatore during his direct examination. When questioned about Saito and Li on cross-examination, Dr. Tornatore's demeanor suggested that the findings of the articles did not matter to him.

In any event, the Saito and Li papers have contrary findings regarding whether fractional anisotropy is increased or decreased in the corpus callosum of OCD patients. Tr. at 353-64. The Koch study referenced by the Secretary corroborates the notion that diffusion tensor imaging studies on OCD patients are heterogenous and much remains to be clarified on the frontier. Exhibit E, tab 6 (Koch). With these limitations, the undersigned is not persuaded that this literature supports Dr. Tornatore's argument that neuroborreliosis can cause OCD.

While Dr. Tornatore's opinion and testimony about Lyme disease causing OCD was far from persuasive, Ms. Elson can find enough support in the reports from doctors who treated Mr. Hodge in the second half of 2009 and beginning of 2010. Because these reports were discussed extensively above (see section IV), they are presented summarily in the following chart.

Date	Medical Personnel	Comment	Cite
10/29/2009	PET scan	"suspected neurolyme"	Exhibit 7 at 178
12/3/2009	Dr. Mathisen, Infectious Disease	"opt to treat for neuroborreliosis"	Exhibit 7 at 22

⁶³ Ms. Elson did not counter this argument about the (lack of) interest in Lyme disease. See Pet'r's Posthear'g Reply.

12/11/2009	Dr. Mathisen, Infectious Disease	“Neuropsychiatric disorder: [patient’s] symptoms are compatible with chronic neurolyme as described in literature.”	Exhibit 14 at 3
12/17/2009	Dr. Dasher, psychiatrist	“currently followed for possible neurolyme with neuropsychiatric [symptoms].”	Exhibit 7 at 37
12/23/2009	Dr. Soaks, attending doctor for discharge summary	“possible neuro-Lyme”	Exhibit 7 at 67-69
12/31/2009	Dr. Mathisen, Infectious Disease	“possible Lyme disease . . . [d]iagnosis is not proven as CSF serology has been negative.”	Exhibit 7 at 21
1/11/2010	Dr. Clough, Infectious Disease	“most likely ... Lyme disease”	Exhibit 13 at 7

Of this group, the parties paid most attention to Dr. Mathisen’s December 11, 2009 report. Tr. at 269, 324, Oral Arg. Tr. at 530.

Evaluating the reports of the treating doctors, including – but not limited to – those listed in the chart is difficult. One dimension of the problem is that the doctors at this time were trying to determine whether Mr. Hodge suffered from Lyme disease. Dr. Clough accurately stated that Mr. Hodge “has had some positive tests for Lyme disease, although Western Blot ... is not confirmatory.” Exhibit 13 at 5. It would seem that until Mr. Hodge is found to have Lyme disease, any opinions about neuro-Lyme would be tentative. Another challenge derives from the variety of problems that Mr. Hodge was reporting. For example, Dr. Mathiesen’s December 3, 2009 report indicates that Mr. Hodge’s problems include a history of OCD and cognitive disturbances from four years ago as well as progressive fatigue, headaches, and memory disturbances. Exhibit 7.1 at 22. He states he will treat Mr. Hodge “for neuroborreliosis.” Similarly, on December 11, 2009, Dr. Mathiesen lists depression, OCD, and changes in cognition as Mr. Hodge’s problems. Exhibit 14.1 at 3. Dr. Mathiesen also states Mr. Hodge’s symptoms “are compatible with chronic neurolyme as described in literature.” *Id.* When Dr. Mathiesen chose to treat Mr. Hodge “for neuroborreliosis,” was Dr. Mathiesen expecting the ceftriaxone and doxycycline to improve all those problems, including the OCD? When asked about this medical record and Dr. Mathiesen’s report, Dr. Venkatesan appeared to indicate that Dr. Mathiesen was linking some (but not necessarily all) Mr. Hodge’s problems to Lyme disease:

[I]n clinical medicine, we do try to be parsimonious when it's reasonable to do so and when the evidence supports that. So I think what this is[,] is an attempt by Dr. Mathisen to try to unify . . . some of the symptoms that have occurred here. And I think that he's an infectious disease doctor and he's trying his best to do that. I think . . . certainly, at this point, I think he feels strongly about antibiotics and feels that they may impact at least some of his symptoms. It's not clear to me that he is negating OCD as an additional possibility here, but it does seem that he is attributing . . . at least some of the neurological psychiatric cognitive changes to Lyme.

Tr. at 441.

Overall, the evidence regarding whether Mr. Hodge's Lyme disease did cause his OCD is mixed. On this topic, the testimony from Dr. Tornatore was neither persuasive nor credible. If the structure for determining whether a vaccine caused a harmful consequence were used to evaluate whether Lyme disease caused Mr. Hodge's OCD, then Mr. Hodge would not have presented persuasive evidence strictly on the prong one question. But, evidence from one Althen prong can affect the outcome on a different Althen prong. Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). As to the etiology of Mr. Hodge's OCD, the reports from treating physicians, which are certainly relevant to Althen prong two, help Ms. Elson establish that Lyme disease can cause OCD. A treating doctor's statement that a vaccine did cause an injury necessarily implies that the vaccine can cause an injury. Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119, 145 (2011), aff'd without op., 463 F. App'x 932 (Fed. Cir. 2012). By this logic, the various reports from Dr. Mathiesen and Dr. Dasher that Mr. Hodge may suffer from "neuroborreliosis" or "neuro-Lyme" are sufficient to establish that those doctors have indicated that Mr. Hodge's psychiatric symptoms could come from his Lyme disease. The reports from treating doctors carry Mr. Hodge's burden for Althen prong two and, effectively, carry his burden regarding Althen prong one.⁶⁴

⁶⁴ The latency between Mr. Hodge's Lyme disease and his OCD is not an issue. Dr. Venkatesan indicated that a person can suffer Lyme disease for months or years before developing late stage neuroborreliosis but acknowledged that late stage manifestations "can occur as early as weeks." Tr. at 426. Dr. Tornatore discussed that the natural history of Lyme neuroborreliosis is one in which symptoms plateau or slowly progress similar to the syphilis without acute relapses. Tr. at 295-98. Thus, the evidence, such as Dr. Clough's report (Exhibit

C. Loving Prongs 2 and 3

The second and third prongs will be taken up together. These elements require an evaluation of “(2) the person’s current condition (or the condition following the vaccination if that is also pertinent), [and] (3) whether the person’s current condition constitutes a ‘significant aggravation’ of the person’s condition prior to vaccination.” Loving, 86 Fed. Cl. at 144. The term “significant aggravation” means “any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.” 42 U.S.C. § 300aa—33(4).

Ms. Elson’s claim that the March and April 2006 vaccinations harmed Mr. Hodge relies in part on the proposition that his mental health deteriorated after vaccination. Pet’r’s Prehear’g Reply at 20-21. In the order for post hearing briefs, regarding significant aggravation, the undersigned stated the following: “Dr. Tornatore’s opinion appears to be that the vaccination caused a host of problems, including (but perhaps not limited to) an eye movement disorder, joint and muscle pain, and sensory problems. An intervening step in this theory appears to be demyelination.” See Order, issued June 17, 2021, at 2. The parties were ordered to address evidence showing Mr. Hodge’s OCD was worse during the summer of 2006.

The undersigned’s reference to “summer of 2006” introduced a question of law as to the relevant time for making a comparison. This issue is resolved first in section VI.C.1 below. After this analysis, the evidence about Mr. Hodge is considered.

1. Legal Issue

Citing Sharpe v. Sec’y of Health & Hum. Servs., 964 F.3d 1072, 1082 (Fed. Cir. 2020), Ms. Elson argued that “Showing that a person’s current condition constitutes a significant aggravation only requires a comparison of a petitioner’s current post vaccination condition with his pre-vaccination condition.” Pet’r’s Posthear’g Br. at 40. Ms. Elson’s emphasis on Mr. Hodge’s current condition led to a question as to whether his current status was the correct point of comparison. See order for oral argument, issued Feb. 10, 2022, ¶ 4.

As originally conceived, the inquiry in step 2 was “the person’s current condition (or the condition following the vaccination if that is also pertinent).”

13 at 5), and the Court’s finding regarding the chronology of events in which Mr. Hodge developed Lyme disease before he manifested OCD symptoms combine to establish the third prong of Althen.

Loving, 86 Fed. Cl. at 144. The Federal Circuit held “that the Loving case provides the correct framework for evaluating off-table significant aggravation claims.” W.C. v. Sec’y of Health & Hum. Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013). The Federal Circuit then quoted the Court of Federal Claims’ six-part test from Loving, including “(2) the person’s current condition (or the condition following the vaccination if that is also pertinent).” Id.

In Sharpe, the Federal Circuit also quoted the Court of Federal Claims’ six-part test from Loving, which contains “(2) the person’s current condition (or the condition following the vaccination if that is also pertinent).” Sharpe, 964 F.3d at 1080. However, as Ms. Elson ably noted, when expounding upon the meaning of Loving prong 3, the Federal Circuit stated that this prong “only requires a comparison of a petitioner’s current, post vaccination condition with her pre-vaccination condition.” Sharpe, 964 F.3d at 1082. The parenthetical phrase “(or the condition following the vaccination if that is also pertinent)” disappeared in this context.

During the March 17, 2022 oral argument, the parties discussed what time is appropriate for Loving prong 2, which is the foundation for Loving prong 3. Ms. Elson argued that the time after the vaccination was not limited:

Whether or not a significant aggravation occurs is not . . . analogous to Althen prong 3, or in this case Loving prong 6, which is reasonable onset. . . I don’t believe that the case law supports a limitation of a few months to demonstrate a significant aggravation.

Oral Arg. Tr. at 536. Ms. Elson added: “to attempt to limit it [meaning significant aggravation] to a specific few months or things after that is – would be arbitrary.” Id. at 537. Later, Ms. Elson asserted: “I don’t think that there’s any restriction in the case law on significant aggravation other than reasonableness.” Id. at 547.

The Secretary disagreed. With respect to the time used in Loving prong 2 as a foundation for Loving prong 3, the Secretary contended “Althen prong 3, Loving prong 6, does sort of play a role.” Oral Arg. Tr. at 539.

On this point, Ms. Elson’s argument is more persuasive as she tracks the precedent. Loving, W.C., and Sharpe all set forth a test in Loving prong three involving the vaccinee’s current condition. Arguably, Sharpe may have gone further and prohibited a special master from considering in Loving prong three, as an alternative, the vaccinee’s “condition following the vaccination.” But, whether the vaccinee’s health closer in time to the vaccination is ever relevant to Loving

prong three need not be resolved here because Ms. Elson's argument is based, at least in part, on Mr. Hodge's "current condition." Pet'r's Posthear'g Br. at 40.⁶⁵

2. Summary of Pertinent Records and Testimony of Mr. Hodge's Condition *Currently*

Based upon how Ms. Elson has focused part of her claim on Mr. Hodge's "current condition," the evidence relevant to Loving prong two and Loving prong three consists primarily of information about how the health of Mr. Hodge currently.⁶⁶ While Ms. Elson has also argued that Mr. Hodge's health declined within 40 days of his hepatitis B vaccination, evidence regarding his health from March 2006 through July 2007 will be discussed more extensively as part of Loving prong five and Loving prong six.

The parties have described Mr. Hodge's current condition in their briefs:

Pet'r's Posthear'g Br.:

Jeremy presented to Dr. Kevin Pimstone at UCLA Health on May 14, 2014. Pet. Ex. 32 at 63. Dr. Pimstone documented Jeremy's history of OCD, depression, and cognitive decline. Id. Dr. Pimstone notes symptoms of ocular migraines, labored breathing, chest pains, abdominal pains, constipation and diarrhea, and joint pains. Id. at 64. Some notable impressions include "Neurocognitive decline," "Abnormal MRI...consistent with possible demyelinating disease," and "Elevated Epstein-Barr antibody." Id. At this time Jeremy was taking hydrocodone, lorazepam, and risperidone. Id. at 60-61. Jeremy was referred to a variety of different specialists including neurologist Dr. Barbara Giesser. Dr. Giesser saw Jeremy on January 21, 2015 and noted

⁶⁵ Thus, the undersigned is altering the position taken in the June 17, 2021 Order. There, the undersigned directed the parties to focus their analysis for Loving prong three on the time within a few months of the vaccination. However, after considering the parties' arguments, the undersigned is persuaded that time for Loving prong three is not restricted.

⁶⁶ In the context of this decision, "current" refers to Mr. Hodge's health in June 2021, when Ms. Elson testified. After that date, Ms. Elson has not submitted any additional evidence. In the absence of any evidence about Mr. Hodge's condition in the intervening approximately two years, the undersigned assumes that Mr. Hodge's current health matches his health in June 2021.

current symptoms of numbness in hands and feet, heat sensitivity, difficulty thinking, and auditory and visual hallucinations. Id. at 781. From 2014 through 2015, Jeremy saw a variety of different doctors at UCLA Health, including a gastroenterologist, an endocrinologist, and a cardiologist. Pet. Ex. 32 at 1590, 1643, 2008.

Jeremy was seen by psychiatrist Dr. James E. Landen for an initial evaluation on March 6, 2015. Dr. Landen gave an assessment of bipolar disorder, psychosis, and reported tardive dyskinesia symptoms. Pet. Ex. 33 at 1. Dr. Landen discussed plans for Jeremy's medication over the phone with his mother throughout 2015 and 2016. Id.

On June 20, 2018, Jeremy was treated in the Emergency Department of West Hills Hospital. Pet. Ex. 59. Jeremy was seen for "chest pain of unclear etiology" and "knee pain NOS." Id.

At trial Ms. Elson testified as to Jeremy's current condition. "He's the same, maybe a little worse, of course. He's worn out. He's tired, the toll that this has taken on him. It's kind of just mentally made him an old man." Tr. at 153. Jeremy is currently seen by Dr. Abrams, who he sees every three months over the telephone due to COVID. Tr. at 155. Jeremy is on these calls, but "he doesn't say much. He doesn't say much to anybody lately. It's been this way for about three years." Tr. at 155. Jeremy is currently taking Risperdal oral solution, Zyprexa for emergencies, Ativan and Klonopin, and Lithium. Tr. at 156. A Zyprexa emergency is if "he becomes very violent or if he becomes—like he just—things just get so bad. His symptoms, you know, the mental health symptoms sometimes can get really bad and it requires an emergency dose of Zyprexa." Id. In the past two years Ms. Elson has had to administer Zyprexa to Jeremy approximately 7 or 8 times. Tr. at 156-157. Finally, Ms. Elson testified that at no point in the intervening 16 years since Jeremy was vaccinated has he

returned to baseline, or his condition prior to vaccination.
Tr. at 157-158.

Pet'r's Posthear'g Br. at 16-17.

Resp't's Posthear'g Br.:

Mr. Hodge established care with a new primary care doctor, Kevin Pimstone, M.D., in May 2014. At that time, he was taking hydrocodone, lorazepam, and risperidone. Pet. Ex. 32 at 56, 63-65. Mr. Hodge's history was recited, including OCD, cognitive dysfunction, personality changes, and occasional psychosis. Id. at 63. After spending 1.5 hours, including interviewing petitioner, interviewing and examining Mr. Hodge, and reviewing medical records, Dr. Pimstone requested that Mr. Hodge return for a complete physical exam so that he could determine what further workup was warranted. Id. at 65. He considered possible referrals to pain medicine, endocrinology, neurology, and ID. Id. Mr. Hodge returned to Dr. Pimstone on several occasions and was seen by a cardiologist, psychiatrist, allergist, ear-nose-and-throat specialist, gastroenterologist, and neurologist throughout the remainder of 2014 and through mid-2015. See, e.g., Pet. Ex. 32 at 285, 689, 781, 1361, 1481, 1559, 1590, 1648, 2008; Pet. Ex. 33.

There are no records of treatment between 2015 and June 2018.

The only record of treatment after 2015 is a visit to the West Hills Hospital emergency room on June 21, 2018, for complaints of chest pain, lumps in his throat, and bilateral knee pain. An x-ray of the neck was unremarkable and x-rays of the knees did not show any acute fracture or dislocation. No etiology of Mr. Hodge's chest pain was found. Pet. Ex. 59.

Resp't's Posthear'g Br. at 20-21.

3. Findings regarding *Loving* prong two and *Loving* prong three

The absence of medical records after 2020 is more understandable because the pandemic made visits, at least in-person visits, to doctors challenging. Mr. Hodge was not getting any medical relief at doctor appointments, which deterred him from seeking further medical attention. Tr. at 154-55.

In the absence of medical records, Ms. Elson's testimony about her son's current condition is an adequate substitute. Ms. Elson's testimony appeared credible when testifying about Mr. Hodge's current abilities. The Social Security Administration has found that he is disabled. Tr. at 193-94. A probate judge from California found that Mr. Hodge required a conservator. Exhibit 28. At the time of Ms. Elson's testimony, Mr. Hodge was prescribed five medications.

In the third step of the *Loving* analysis, a special master compares the vaccinee's condition before the vaccination to the vaccinee's condition currently. The purpose is to determine whether the vaccinee has experienced "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4) (defining "significant aggravation").

Despite some uncertainty, Ms. Elson has met her burden with preponderant evidence. The undersigned is uncertain whether Mr. Hodge's condition soon worsened after the receipt of the vaccination because of a lack of persuasive and reliable information about his health before the vaccination. For example, the Court's determination that Mr. Hodge suffered from OCD before September 28, 2004 relied, in part, upon Mr. Hodge's lack of return to high school for his eleventh grade. Second Opinion and Order, 164 Fed. Cl. 633, 647 (2023). Similarly, the Court cited, among other evidence, Dr. Nasse's prescription of two medications around September 28, 2004. Id. This information suggests that OCD was impairing an activity that Mr. Hodge would normally perform (attend school) and required medication. Thus, even before the vaccination, Mr. Hodge's OCD was causing him problems. See Exhibit 21 (Ms. Elson's Oct. 16, 2015 affidavit) at 1 ("His OCD made him fall too far behind in school to keep up with ordinary classes. Because of his condition, ordinary high school overwhelmed him."). More evidence, particularly medical records from Dr. Nasse and West Valley Mental Health where he was treated for OCD, would have clarified Mr. Hodge's health before the vaccination.

On the other hand, Ms. Elson is not required to present her case with certainty or convincingly. Her burden of proof is merely more likely than not.

Under that standard, Ms. Elson has shown that Mr. Hodge currently is worse than he was before he received the vaccinations.

D. Loving Prong 4

The fourth Loving prong corresponds to the first Althen prong, meaning the focus is whether a petitioner has presented sufficient evidence to establish a theory by which a vaccine can cause (or can aggravate) a condition.⁶⁷ This element is sometimes referred to as “general causation,” because the characteristics of the vaccinee are not involved. See Snyder v. Sec’y of Health & Hum. Servs., 88 Fed. Cl. 706, 719-20 (2009) (discussing general causation in the context of the omnibus autism proceeding); Piscopo v. Sec’y of Health & Hum. Servs., 66 Fed. Cl. 49, 54 (2005); see also Rowan v. Sec’y of Health & Hum. Servs., No. 10-272V, 2015 WL 3562409, at *5 (Fed. Cl. May 18, 2015) (“General causation is not petitioner specific.”).

Dr. Tornatore, Ms. Elson’s expert, “puts forth the concept of molecular mimicry as the underlying mechanism resulting in [Mr. Hodge’s] autoimmune demyelination.” Pet’r’s Posthear’g Br. at 52. The analysis within this section begins with a brief overview of the burden of proof required and addresses the value of previous cases examining whether vaccines can cause (or aggravate) demyelinating conditions. It then discusses the evidence regarding the theory of molecular mimicry. Two propositions are explored: whether Lyme disease neuroborreliosis is an autoimmune demyelinating disease and whether the hepatitis B vaccine can lead to an attack on myelin.

1. Legal Burden

The parties dispute the legal standard regarding plausible vs. preponderant evidence. Ms. Elson argues her burden under Althen prong 1 can be satisfied by demonstrating a “biologically plausible theory” “supported by ‘reputable medical or scientific explanation.’” Pet’r’s Posthear’g Br. at 21 (quoting Althen, 418 F.3d at 1278 and citing Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1375 (2009)). The Secretary disagrees, arguing that merely showing a “plausible” or “possible” causal link between vaccination and injury is insufficient to satisfy the

⁶⁷ Under the heading of “Loving prong 4,” the parties also discussed Mr. Hodge’s condition. See Pet’r’s Posthear’g Br. at 48-51; Resp’t’s Posthear’g Br. at 54, 57-59. While evidence on one prong may be relevant to another prong, Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006), evidence about Mr. Hodge’s health after the vaccination is discussed as part of Loving prong 5 below.

preponderance standard. Resp’t’s Posthear’g Br. at 22, 57 (citing Boatmon v. Sec’y of Health & Hum. Servs., 941 F.3d at 1360).

The Vaccine Act requires a petitioner to:

show by preponderant evidence that the vaccination brought about [his] injury by providing (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Bull v. Sec’y of Health & Hum. Servs., 156 Fed. Cl. 329, 335 (2021) (citing to Boatmon v. Sec’y of Health & Hum. Servs., 941 F.3d 1351, 1355 (Fed. Cir. 2019) (noting that a petitioner must “*prove[] all three Althen prongs by a preponderance of the evidence*”)) (emphasis added). “Under the first prong, a petitioner must demonstrate that the vaccine at issue can cause the injury alleged.” Bull, 156 Fed. Cl. at 335. To satisfy this element, a “petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner’s case, although the explanation need only be ‘legally probable, not medically or scientifically certain.’” Id. (quoting Broekelschen v. Sec’y of Health & Hum. Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010)) (citation omitted).

2. Precedent Cases

Special masters are familiar with the theory of molecular mimicry. See, e.g., Katz v. Sec’y of Health & Hum. Servs., No. 04-714V, 2005 WL 6117659, at *11-18 (Fed. Cl. Spec. Mstr. Nov. 30, 2005) (summarizing testimony of a petitioner’s expert); Bubb v. Sec’y of Health & Hum. Servs., No. 01-721V, 2005 WL 1025707, at *11-14 (Fed. Cl. Spec. Mstr. Apr. 25, 2005) (summarizing testimony of a petitioner’s expert).

Given the frequency that special masters have evaluated the theory of molecular mimicry, the Court of Federal Claims and the Court of Appeals for the Federal Circuit have considered molecular mimicry in their appellate role opinions from special masters. In December 2019, the undersigned identified the leading precedents as W.C. v. Sec’y of Health & Hum. Servs., 704 F.3d 1352 (Fed. Cir. 2013), and Caves v. Sec’y of Health & Hum. Servs., 100 Fed. Cl. 119 (2011), aff’d without opinion, 463 F. App’x 932 (Fed. Cir. 2012). Tullio v. Sec’y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *12-14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020). While Tullio describes

those cases in more detail, their essence appears to be that although molecular mimicry is accepted in some contexts, special masters may properly require some evidence to show that a particular vaccine can cause a particular disease.

In the next three years, appellate authorities reviewing decisions involving molecular mimicry have generally endorsed the approach of looking for some evidence that persuasively shows that a portion of a vaccine resembles a portion of human tissue, which contributes to causing the disease, and that the immune system will respond to the relevant amino acid sequence.⁶⁸ Chronologically, the list of more recent appellate cases begins with the opinion in Tullio, which denied the motion for review. 149 Fed. Cl. 448, 467-68 (2020).

Another example in which the Court of Federal Claims held that the special master did not elevate the petitioner's burden of proof in the context of evaluating the theory of molecular mimicry is Morgan v. Sec'y of Health & Hum. Servs., 148 Fed. Cl. 454, 476-77 (2020), aff'd in non-precedential opinion, 850 F. App'x 775 (Fed. Cir. 2021). In Morgan, the Chief Special Master found that petitioner had not presented persuasive evidence about a relevant antibody. Id. at 477. The Chief Special Master also noted that the articles about the relevant disease do not list the wild flu virus as potentially causing the disease. Id. When examining this analysis, the Court of Federal Claims concluded: "the Chief Special Master did not raise the burden of causation in this case; petitioner simply failed to meet it." Id.

The Federal Circuit also evaluated the Chief Special Master's approach in Morgan. The Federal Circuit concluded: "We discern no error in the special master's causation analysis." 850 F. App'x 775, 784 (Fed. Cir. 2021).

Most other recent appellate cases follow this path. See, e.g., Duncan v. Sec'y of Health & Hum. Servs., 153 Fed. Cl. 642, 661 (2021) (finding the special master did not err in rejecting a bare assertion of molecular mimicry); Caredio v. Sec'y of Health & Hum. Servs., No. 17-79V, 2021 WL 6058835, at *11 (Fed. Cl. Dec. 3, 2021) (indicating that a special master did not err in requiring more than homology and citing Tullio); Yalacki v. Sec'y of Health & Hum. Servs., 146 Fed. Cl. 80, 91-92 (2019) (ruling that special master did not err in looking for reliable evidence to support molecular mimicry as a theory); but see Patton v. Sec'y of Health & Hum. Servs., 157 Fed. Cl. 159, 169 (2021) (finding that a special master erred in requiring petitioner submit a study to establish medical theory causally connecting flu vaccine to brachial neuritis).

⁶⁸ The term "homology" is used when discussing molecular mimicry. "Homology" is defined as "the quality of being homologous; the morphological identity of corresponding parts; structural similarity due to descent from a common form." Dorland's at 868.

In her brief, Ms. Elson emphasizes the findings of one special master that ruled on multiple cases in the hepatitis B – Demyelinating Diseases Omnibus proceedings. Pet’r’s Posthear’g Br. at 51, citing Werderitsch v. Sec’y of Health & Hum. Servs., No. 99-310V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006); Gilbert v. Sec’y of Health & Hum. Servs., No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006); and Stevens v. Sec’y of Health & Hum. Servs., No. 99-594V, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006). Ms. Elson seems to argue that because other petitioners prevailed in showing a hepatitis B vaccine caused their specific demyelinating condition (e.g., GBS, CIDP, and TM), there is sufficient justification to find the hepatitis B vaccine can cause Mr. Hodge’s condition (i.e. significant aggravation of Lyme disease neuroborreliosis). However, a special master’s fact-findings in other cases do not dictate the same result in different cases. Boatmon v. Sec’y of Health & Hum. Servs., 941 F.3d 1351, 1358 (2019) (reaffirming that special masters are not bound to follow the opinions of other special masters).

One reason an outcome before one special master does not bind another special master is the evidence might differ. The evidence submitted in the demyelinating proceedings was much more extensive than the evidence submitted in Ms. Elson’s case. (The scant evidence regarding the potential harmful effects of the hepatitis B vaccine is reviewed in section VI.D.3 below.) Special masters are not required to distinguish non-binding decisions of other special masters. Id. However, by way of example, in Stevens, the petitioners “submitted approximately 300 medical articles, case notes, letters in medical journals, etc.” Stevens, 2006 WL 659525, at *8.⁶⁹ Petitioners presented the testimony of not just Dr. Tornatore but also two other experts. Id. at *10-20 (summarizing testimony of petitioners’ three witnesses as well as testimony of respondents’ three witnesses). Ms. Stevens also enjoyed support from the opinions of two doctors who treated her in the context of a workers’ compensation claim. Id. at *22. A disparity in the quality and quantity of evidence can justify a difference in outcome.

Furthermore, a slightly contrary finding was made in W.C. v. Sec’y of Health & Hum. Servs., No. 07-456V, 2011 WL 4537877 at *12-16, mot. for rev. denied, 100 Fed. Cl. 440, 454-56 (2011), aff’d, 704 F.3d 1352, 1360-61 (2013). There, Dr. Tornatore and Dr. Venkatesan testified and disagreed whether an influenza vaccine can cause demyelination via molecular mimicry. The (undersigned) special master determined that W.C. had not presented persuasive

⁶⁹ Stevens serves as the basis for comparison because the Stevens evidence was incorporated into the decisions in the other two cases. Werderitsch, 2006 WL 1672884, at *1, and *8 n.5; Gilbert, 2006 WL 1006612, at *1, and *6.

proof that the influenza vaccine can aggravate a demyelinating disease (multiple sclerosis). Upon review, the Federal Circuit ruled that the determination was not arbitrary or capricious. The Federal Circuit stated that the “special master found that ‘[m]olecular mimicry is a well-regarded theory in some contexts,’ . . . but correctly required additional evidence showing that molecular mimicry can cause the influenza vaccine to significantly aggravate multiple sclerosis.” 704 F.3d at 1360 (citation omitted). Thus, compared to rulings from the hepatitis B – Demyelinating Conditions omnibus proceeding, as a matter of precedent, the special master’s *methodology* in W.C. merits additional weight because of appellate review.

However, the outcome in W.C. (a denial of compensation) does not dictate the same result here. Although W.C. involved the same experts, the vaccinations differed—influenza vaccine in W.C. and hepatitis B vaccine here. Moreover, the Federal Circuit’s ruling that a special master’s finding regarding (a lack of) causation was not arbitrary and capricious does not prevent a different finding in a different case. See Bean-Sasser v. Sec’y of Health & Hum. Servs., 127 Fed. Cl. 161, 167 (2016). Ultimately, Ms. Elson’s case turns on the evidence presented in it.

While W.C. underwent appellate review and was affirmed by the Federal Circuit, hence providing some guidance on how to approach cases in which petitioners present the theory of molecular mimicry, no appellate authority reviewed the methodology or outcome in Stevens, Gilbert, or Werderitsh. Thus, how an appellate authority might have evaluated the special master’s finding that a hepatitis B vaccine can cause demyelinating conditions is unknown. Similarly, in the present case, the Court has not offered any opinions or comments regarding the value of the evidence supporting or refuting the claim that a hepatitis B vaccination can cause (or aggravate) demyelination. The September 12, 2022 Entitlement Decision did not analyze the theory of molecular mimicry. See First Entitlement Decision, 2022 WL 4954672, at *1 (Fed. Cl. Spec. Mstr. Sept. 12, 2022). It follows that the Second Opinion and Order also did not comment on the theory of molecular mimicry. See Second Opinion and Order, 164 Fed. Cl. 633 (2023). Therefore, the present case’s evidence regarding molecular mimicry needs to be examined for the first time as part of the remand. “Upon return of its mandate, the district court cannot give relief beyond the scope of that mandate, but it may act on matters left open by the mandate.” Laitram Corp. v. NEC Corp., 115 F.3d 947, 951 (Fed. Cir. 1997) (quoting Caldwell v. Puget Sound Elec. Apprenticeship & Training Tr., 824 F.2d 765, 767 (9th Cir. 1987)) (internal quotation marks omitted).

3. Evidence regarding Theory of Molecular Mimicry

Dr. Tornatore presents two contentions in support of Mr. Hodge's case, namely that the Lyme disease neuroborreliosis is an autoimmune demyelinating disease and that the hepatitis B vaccine can significantly aggravate Lyme disease neuroborreliosis via molecular mimicry. The evidence, when considered as a whole, does not preponderate in favor of finding Dr. Tornatore's points persuasive.

a) Is Lyme disease neuroborreliosis an autoimmune demyelinating disease?

Ms. Elson contends that Lyme disease neuroborreliosis is an autoimmune condition, like multiple sclerosis in which the person's myelin is attacked. Pet'r's Posthear'g Br. at 50-51; see also Exhibit 29 at 8. From that premise, Ms. Elson compares her case to other cases in which a special master has found that a hepatitis B vaccination can cause demyelinating diseases, such as multiple sclerosis.

As to whether neuroborreliosis is an autoimmune demyelinating disease, the evidence is mixed. Dr. Tornatore, himself, recognized that his attempt to characterize neuroborreliosis as autoimmune was a "complicated part" of his opinion because "[t]his is where infectious disease and neuroimmunology crossover." Tr. at 18. He acknowledged that the "symptoms of Lyme disease –late stage being the neurologic symptoms, the psychiatric symptoms – [could easily be] due to persistent infection or to post-infectious immune activation." Tr. at 20.

The primary articles on which Dr. Tornatore relied for this opinion were Exhibit 42 (Hildenbrand) and Exhibit 43 (Ramesh).⁷⁰ Hildenbrand is a review article, published in 2009. Exhibit 42 at 1079 (Hildenbrand). The authors consider "the diagnosis and clinical spectrum of Lyme neuroborreliosis (LNB), with special attention to the varying features of corroborative diagnostic neuroimaging." Id. One way neuroborreliosis can present is in the central nervous system. In this context, the "putative mechanisms for LNB [Lyme neuroborreliosis] CNS [central nervous system] injury include vasculitis, cytotoxicity, neurotoxic mediators, or

⁷⁰ Ms. Elson asserts that "the experts agree that neuroborreliosis symptoms can be aggravated by external triggers that stimulate an inflammatory cascade. Pet. Ex. 34 at 1; Pet. Ex. 29 at 8; Tr. at 381. Hildenbrand, et al. also supports this assertion. See Pet. Ex. 42." Pet'r's Posthear'g Reply at 21. Exhibits 29 and 34 are reports from Dr. Tornatore and while they do support the proposition that Dr. Tornatore opined that external factors may trigger neuroborreliosis symptoms, Dr. Venkatesan's testimony on page 381 of the transcript does not actually discuss external triggers.

autoimmune reaction via molecular mimicry.” Id. at 1083. Citing a paper that is not an exhibit in this case, the authors seem to dismiss, as speculation, molecular mimicry because “T-cell lines demonstrate only weak cross-reactivity between myelin basic protein and *B burgdorferi*.” Id.

In discussing the ways neuroimaging can assist with diagnosis of CNS LNB, the authors explain typical findings on an MRI. Id. Dr. Tornatore, in turn, quotes a portion of the abstract, which states “‘The MR imaging white matter appearance of successfully treated Lyme Neuroborreliosis and multiple sclerosis display sufficient similarity to suggest a common autoimmune pathogenesis for both.’” Exhibit 29 at 8, quoting Exhibit 42 at 1079; accord Tr. at 91. On cross-examination, Dr. Tornatore recognized that similar MRI patterns do not establish a common autoimmune pathogenesis. Id. at 95-96.

To reinforce his contention that neuroborreliosis is an autoimmune demyelinating disease, Dr. Tornatore pointed to the Ramesh article. Tr. at 98. The title of the Ramesh article, which was published in 2015, is “Inflammation in the Pathogenesis of Lyme Neuroborreliosis.” Exhibit 43 at 1344 (Ramesh). The Ramesh researchers conducted a complicated experiment, which Dr. Tornatore and Dr. Venkatesan tried to explain. Tr. at 93-99 (Dr. Tornatore’s cross-examination), 104 (Dr. Tornatore’s cross-examination), 376-77 (Dr. Venkatesan’s direct), 417-26 (Dr. Venkatesan’s response to questions from the special master), 458-59 (Dr. Tornatore’s rebuttal).⁷¹ The Ramesh researchers showed that an infection with the spirochete leads to inflammation and inflammation can be harmful. Id. at 420. This is not surprising, and the title of the article indicates it is about inflammation. In contrast, the article does not use the term “autoimmunity.” Id. at 376. As Dr. Venkatesan persuasively explained, the presence of immune cells does not necessarily mean that an injury’s etiology is autoimmune. Id. at 377.

Ultimately, Dr. Tornatore recognized that researchers are considering multiple mechanisms, not just autoimmunity, as ways to explain how neuroborreliosis develops. Tr. at 292; see also Tr. at 290 (predicate question). Additionally, as discussed in section III, Dr. Venkatesan has a stronger background in Lyme disease because he works at a center for studying Lyme disease. Tr. at 341. Thus, his careful definition of autoimmunity and his opinion that the Ramesh article does not show autoimmunity carry persuasive value.

⁷¹ In their submissions after the hearing, the parties’ discussions of these articles were relatively short. See Pet’r’s Posthear’g Br. at 50-51, Resp’t’s Posthear’g Br. at 42-43, Pet’r’s Posthear’g Reply at 21. They do not summarize the Ramesh experiments and the briefs do not summarize much of the testimony from the experts.

Under these circumstances, Ms. Elson has not established that neuroborreliosis is an autoimmune condition. As discussed in the following section, even if it were found that neuroborreliosis is an autoimmune demyelinating condition, Dr. Tornatore has not persuasively established that the hepatitis B vaccine can lead to an attack on myelin.

b) Can the hepatitis B vaccine cause an autoimmune demyelinating disease?

The dispositive issue is whether the hepatitis B vaccine can cause (or aggravate) an autoimmune demyelinating disease. Dr. Tornatore proposes that the vaccine can cause a demyelinating disease. Dr. Venkatesan, on the other hand, disagrees.

Although the undersigned has reviewed the entire record, the analysis will primarily focus on the evidence that Ms. Elson cites as most supportive of her case. Ms. Elson argues that “Dr. Tornatore elaborates on the reputable science supporting this theory [that the hepatitis B vaccination can lead to autoimmune demyelination]. See Pet. Ex. 29; See also Pet. Ex. 48-51; Tr. at 31-32.” Pet’r’s Posthear’g Br. at 51.⁷² The items of evidence Ms. Elson has identified are: exhibit 29, which is Dr. Tornatore’s January 22, 2017 report; four articles filed as exhibits 48-51; and Dr. Tornatore’s testimony found in two pages of the transcript.⁷³

⁷² In another portion of her brief, Ms. Elson contends that Exhibits 39-55 support Dr. Tornatore’s theory. Pet’r’s Posthear’g Br. at 56. Some of those articles do not carry much weight in considering whether the hepatitis B vaccine can cause or aggravate a demyelinating condition. Exhibit 39 concerns the frequency of OCD in people with multiple sclerosis. Exhibits 40-44 discuss neuroborreliosis. Exhibit 52 presents information about the increased incidence of Guillain-Barré syndrome after the 1976-77 swine flu immunization program. Exhibit 53 discusses acute disseminated encephalomyelitis. Exhibits 54-55 presents information about multiple sclerosis. Thus, while these articles have been considered, they are not discussed in this portion of the decision, which concerns the hepatitis B vaccination.

⁷³ Ms. Elson also points to Dr. Venkatesan’s statement that “molecular mimicry is a valid theory to explain the basis of some autoimmune diseases.” Pet’r’s Posthear’g Br. at 55, quoting Exhibit E at 5. This statement resembles Dr. Venkatesan’s agreement in W.C. that “molecular mimicry is accepted as playing a role in the autoimmune disease Sydenham’s chorea.” W.C., 704 F.3d at 1360. Similarly, Dr. Venkatesan’s testimony that a vaccine causing a demyelinating injury as a “possibility” (Tr. at 400) does not meaningfully advance Ms. Elson’s effort to carry her burden. See Moberly, 592 F.3d at 1322 (indicating that “possible” does not meet petitioner’s burden of proof); Paterek v. Sec’y of Health & Hum. Servs., 527 F.App’x 875, 883 (Fed. Cir. 2013) (“testimony that causation was ‘not impossible’ fails to provide support for causation at all”); M.S.B v. Sec’y of Health & Hum. Servs., 117 Fed. Cl. 104, 125 (2014) (“not excluding a

Dr. Tornatore's January 22, 2017 report covers multiple topics, including his qualifications, his review of material, a summary of the medical records, a description of neuroborreliosis, a description of obsessive-compulsive disorder, and an analysis of the temporal interval. See Exhibit 29. Within that twelve-page report, Dr. Tornatore's opinion regarding how the hepatitis B vaccine might harm a recipient is found in one paragraph:

Is it biologically plausible for the hepatitis B vaccine to cause autoimmune demyelination? Vaccinations are composed of organic compounds of viral or bacterial origin, recombinant or otherwise, which are meant to stimulate an immune response once injected. If the antigens present on the vaccine share any homology with host antigens, then the immune response will be directed at both the injected antigens and host antigens, leading to an autoimmune response. The concept that viral or bacterial antigens share homology with host antigens, also known as molecular mimicry, is a well-established concept in immunology (9). With regards to this case, a number of papers have examined the plausibility that antigens present in the hepatitis B vaccine could lead to immunologic cross reactivity with myelin leading to autoimmune demyelination. (10-14). An interesting case report by Matsui and colleagues (15) reported the case of a 46-year-old man with extremely high titers to hepatitis B surface antigen (due to hepatitis B infection) who had 3 attacks of acute demyelination. Once the patient was treated, circulating immune complexes of hepatitis B surface antigen disappeared. The authors concluded "In light of the animal studies demonstrating autoimmunity triggered by molecular mimicry between MBP and hepatitis B virus antigen, this patient may serve as a rare example of CNS demyelination in humans with the same autoimmune etiology."

Exhibit 29 at 10.

possibility is far from conceding a probability. The preponderance of the evidence standard requires more than proof of a mere possibility"). Thus, for Ms. Elson to carry her burden, she must succeed with the opinion from the expert she retained, Dr. Tornatore.

In this passage, Dr. Tornatore has cited a series of references. These are:

Articles Dr. Tornatore Has Cited in Support of Molecular Mimicry		
Dr. Tornatore's Reference Number	Lead Author's Last Name	Exhibit within Ms. Elson's Case
9	Oldstone	47
10	Bogdanos	48
11	Waisbren	49
12	Comenge	50
13	Comenge (duplicate)	50 (duplicate)
14	Comenge (duplicate)	50 (duplicate)
15	Matsui	51

The Bogdanos, Waisbren, Comenge, and Matsui articles (exhibits 48-51) are the articles Ms. Elson has identified in her brief. In the portion of Dr. Tornatore's testimony that Ms. Elson cites as supporting his opinion regarding molecular mimicry, Dr. Tornatore also referenced those articles:

Q. All right. You talked about your theory of causation briefly, thank you for that, and it is referenced extensively in your expert reports.^[74] I do want to ask a couple of questions with respect to that. One, just to clarify and have it on the record again, what scientific

⁷⁴ This question indicates that Dr. Tornatore discussed his theory of causation "extensively" in more than one report. However, that description may not be accurate. Dr. Tornatore wrote five reports. Exhibit 18, which is essentially two pages, talks about Mr. Hodge's disease and when his disease began. This report was presented when the parties were debating whether the statute of limitation bars the action. Dr. Tornatore concluded this report by offering "to submit another report in this case discussing the vaccine-related aggravation of his symptoms from neuroborreliosis if you feel that it is necessary."

Exhibit 29 is Dr. Tornatore's report that presents his opinion on causation. The relevant paragraph is quoted in the text above.

Exhibit 34 is another two-page report. One paragraph discusses molecular mimicry without adding more articles. Exhibit 34 at 2.

Exhibit 35 discusses the expected course of OCD over two pages. Dr. Tornatore does not discuss causation in this report.

Exhibit 83 is a much lengthier report (19 pages). Dr. Tornatore reviews material from Mr. Hodge's medical history based upon information gathered after his earlier reports. This report does not discuss molecular mimicry.

evidence is there that the hepatitis B vaccination is linked to or can cause inflammatory demyelinating diseases?

A. So I submitted, I think, four or five papers that really looked at this to show that there is homology between hepatitis B antigens, as well as homology with those antigens and myelin basic protein and myelin-associated glycoprotein, MOG. And a number of those papers looked at this in vivo where the patients post-vaccination were looked at and found to have antibodies that cross-reacted against both the hepatitis B antigen, as well as the myelin basic protein, so tying together the concept that you can develop antibodies to the hepatitis B antigens and that those antibodies will cross-react to myelin-associated proteins. I also submitted an interesting case report of a patient that had ongoing hepatitis B surface antigenemia, so a continuous antigen production. And that triggered his immune system numerous times and developed inflammatory disease. And the authors specifically stated that they thought that the hepatitis B surface antigen was the nidus or the trigger for the central nervous system inflammation, again tying together this idea of in vivo cross-reactivity, not simply something that is theoretical.

Tr. at 31-32.

A foundational article is the Oldstone article. Exhibit 47 (Oldstone). It is summarized first below. Then, the other articles regarding either the hepatitis B virus or the hepatitis B vaccine to which Dr. Tornatore referred and to which Ms. Elson cited will be discussed in chronological order, starting with the earliest.

Oldstone: This article reports and summarizes information about molecular mimicry as of the date of its publication in 2005. Oldstone notes that his partner (Fujinami) and he defined molecular mimicry in 1983. Exhibit 47 at 2-3 (Oldstone). One method of detecting homologies is by “computer searches to match proteins described in storage banks.” *Id.* at 3. According to Oldstone, “it is now abundantly clear that molecular mimicry occurs between proteins encoded by numerous microbes and host self-proteins and is rather common.” *Id.* One example is a similarity between streptococcus and heart valves. *Id.*

The finding of a match via a computer search appears not to end the evaluation. Oldstone states: “immunochemical analysis of cross-reactive epitopes has revealed that reactivity can be dependent on a single amino acid, so experimental evidence is required to support computerized identification of a sequence fit.” Id. at 5 (citations omitted without notation).

As an example of experimental evidence, Oldstone pointed to a study Fujinami and he conducted in 1985. There, they discovered homology between the hepatitis B virus polymerase and myelin basic protein. Id. at 7. When the researchers injected rabbits with the hepatitis B virus polymerase, some rabbits developed disease within their central nervous system. Id.⁷⁵ “However this model was artificial, because there was no epidemiological evidence associating hepatitis B with an EAE-like disease.” Id. at 7-8.

Oldstone acknowledged that: “The most difficult step in the process described here is to definitively prove the relevance of molecular mimicry to human autoimmune disease. Various correlations ranging from those that are reasonably convincing to those that are less so have been published.” Exhibit 47 at 10 (Oldstone). In the summary portion of this article, Oldstone explained his understanding of molecular mimicry in 2005. He stated: “In conclusion, molecular mimicry is but one mechanism by which autoimmune diseases can occur in association with infectious agents.” Id. at 13. Oldstone characterized molecular mimicry as a hypothesis: “The concept of molecular mimicry remains a viable hypothesis for framing questions and approaches to uncovering the initiating infectious agent as well as recognizing the ‘self’-determinant, understanding the pathogenic mechanism(s) involved, and designing strategies for the treatment and prevention of autoimmune disorders.” Id. Oldstone even quoted the Oxford Dictionary to define “hypothesis,” as “‘a supposition or conjecture put forward to account for certain facts and used as a basis for further investigation by which it may be proved or disproved.’” Id. In terms of the degree to which molecular mimicry has been assessed, Oldstone indicated: “In many instances, hard data derived in experimental systems clearly indicate molecular mimicry as a mechanism for disease causation. For others, especially human disorders, the

⁷⁵ Special masters have discussed this 1985 article. See D.G. v. Sec’y of Health & Hum. Servs., No. 11-577V, 2019 WL 2511769, at *73 (Fed. Cl. Spec. Mstr. May 24, 2019); Abbott v. Sec’y of Health & Hum. Servs., No. 99-497V, 2010 WL 3186269, at *11 (Fed. Cl. Spec. Mstr. June 28, 2010); Katz v. Sec’y of Health & Hum. Servs., No. 04-714V, 2005 WL 6117659, at *12 n.38. However, the first article presenting the results of this experiment is not in evidence here. Thus, the information about the experiment is derived from Oldstone’s 2005 summary.

evidence can be strongly suggestive, but additional information is required before molecular mimicry can be accepted or rejected as biological reality.” Id.⁷⁶

Matsui: This 1995 article reports on the experience of one patient. The patient had developed “severe lumbar pain and weakness in the lower extremities, and subsequently experienced retention of urine and feces over the following two days.” Exhibit 51 at 235 (Matsui). Testing during hospitalization revealed that the patient carried hepatitis B surface (“HBs”) antigens but did not have active hepatitis. Id. at 236. The patient also had high amounts of myelin basic protein in his cerebrospinal fluid. Id. “The patient was diagnosed with demyelinating transverse myelitis and associated aseptic meningitis, and was treated with intravenous high-dose methylprednisolone.” Id. He then improved. A year or more later, “the patient had two episodes of recurrence of myelitis.” Id.

In their discussion, the authors considered but appeared to reject that the patient suffered from multiple sclerosis. Id. at 237. The authors stated “it would be pertinent to consider an excessive amount of HBs antigen in the blood as another possible etiology.” Id. They explained: “the presence of antibodies to HBV [hepatitis B virus] antigens implies the possibility of immunity against other components of HBV such as DNA polymerase. . . . In this regard, the persistence of HBV components including HBs antigen in the CSF / CNS of the patient may contribute to the recurrent demyelinating lesion formation in the CNS.” Id.

Matsui is a case report. In general, case reports provide little, if any, information helpful to determining causation because they present only a temporal sequence of events in which the vaccination preceded an adverse health event. See K.O. v. Sec’y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July 7, 2016) (discussing appellate precedent on case reports); Bubb, 2005 WL 1025707, at *21 (quoting a report from the Institute of Medicine saying “Case reports and case series are generally inadequate by themselves to establish causality”). Matsui is even more attenuated because the authors do not indicate that the subject of their case report received the hepatitis B vaccination. See Exhibit 51 (Matsui).

Bogdanos: This team of researchers “looked for amino [] acid similarities between the small hepatitis B virus surface antigen (SHBsAg), and the MS-autoantigens myelin basic protein (MBP) and myelin oligodendrocyte glycoprotein (MOG) that could serve as targets of immunological cross-reactivity.” Exhibit 48

⁷⁶ Ms. Elson quotes the first sentence regarding “hard data,” but does not quote the second sentence regarding the requirement for “additional information.” See Pet’r’s Posthear’g Br. at 52.

at 217 (Bogdanos). The researchers used the Blast program to search for amino acid similarity between the SHBsAg and either MBP or MOG. Id. at 218. This search revealed some similarities over various spans. Id. at 219 (Fig. 1).⁷⁷ The researchers also obtained 234 serum samples of which some were gotten from before vaccination, some from after vaccination, and some from controls. Id. at 218. The results showed that 60% of vaccinees “had SHBsAg/MOG double reactivity on at least occasion.” Id. at 217; accord Tr. at 253. “None of the vaccinees reported symptoms of demyelinating disorders.” Exhibit 48 at 222 (Bogdanos).

In the authors’ discussion, they commented that: “The question of a connection between vaccination and autoimmune disorders is surrounded by controversy. . . . A heated debate is going on regarding the causality between anti-HBV vaccination and demyelinating disorders such as multiple sclerosis.” Id. “All of the vaccinees were free of autoimmune phenomena before vaccination and remain free of any adverse reactions during the follow up.” Id. at 222-23.

The authors cast their conclusion in uncertain terms. “Clues as to the pathogenic link between the vaccine and specific autoimmune disorders, therefore, could not be established.” Id. at 223. The findings in this study “suggest that upon vaccination, induction of an anti-viral response is initially capable of promoting cross-reactive anti-self immune responses, which decrease over time, possibly as a result of peripheral tolerance mechanisms. This scenario may explain why very rarely adverse postvaccination autoimmune reactions occur.” Id. “In view of the observed SHBsAg/MOG cross-reactivity, the vaccine’s possible role as a trigger for the induction and/or maintenance of viral/self cross-reactivity through molecular mimicry must be further investigated.” Id.

On direct examination, Dr. Tornatore spoke very little about this article. Although the article was not named, Dr. Tornatore was referring to Bogdanos when he testified that “a number of those papers looked at this in vivo where the patients post-vaccination were looked at and found to have antibodies that cross-reacted against both the hepatitis B antigen, as well as the myelin basic protein.” Tr. at 31. On cross-examination, Dr. Tornatore correctly conceded that none of the people who cross-reacted developed disease. Tr. at 254. However, Dr. Tornatore predicted that a disease might show up in a study with “millions of people.” Id. Dr. Tornatore’s prediction that a larger study, involving millions of people, would find more instances of diseases appears not to be based upon anything. This

⁷⁷ According to some non-binding appellate precedents, an explicit identification of homology does not always fulfill a petitioner’s burden. Yalacki, 146 Fed. Cl. at 92; see also Duncan, 153 Fed. Cl. at 661; Caves, 100 Fed. Cl. at 135.

testimony does not have to be credited. See Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997); see also Moberly ex rel. Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315 (Fed. Cir. 2010); Snyder ex rel. Snyder v. Sec’y of Health & Hum. Servs., 88 Fed. Cl. 706, 743-44 (2009).

Comenge and Girard: The fourth article, which is written by Yannick Comenge and Marc Girard, does not present any original research. Exhibit 50 (Comenge). Instead, the authors appear to summarize some research that, in their view, supports their hypothesis that the “hepatitis B vaccine . . . has a marked potential to induce auto-immune hazards, neurological as well as non-neurological.” Id. at 84. These authors cited a paper by E. Faure, which is not part of the record in Ms. Elson’s case. The Faure article, as summarized by Comenge and Girard, makes “the quite credible hypothesis that the manufacturing process could leave minute amounts of HBV polymerase protein as a contaminant.” Id. at 85. Comenge and Girard end by suggesting that the potential benefits of vaccination against hepatitis B be reevaluated. Id. at 86.

Waisbren: The most recent of the five articles Dr. Tornatore cited was published in 2008. Burton Waisbren appears to hypothesize that the hepatitis B vaccine when given to a person who already is infected with the Epstein-Barr virus may develop multiple sclerosis via molecular mimicry. Exhibit 49 (Waisbren).⁷⁸ Waisbren proposes two experiments to test this hypothesis: (1) determining whether “the capsular antigen of the hepatitis B vaccine has chemical complementarity with the Epstein-Barr virus,” and (2) injecting the hepatitis B vaccine and an appropriate virus into “genetically appropriate mice with adjuvant to see if ‘experimental allergic encephalitis’ follows.” Id. at 4.

The last two of the papers (Comenge and Waisbren) do not present any experiments. They appear to present hypotheses. (The journal that published both articles is called “Medical Hypotheses”.⁷⁹) See Borrero v. Sec’y of Health & Hum. Servs., No. 01-417V, 2008 WL 4527837, at *12 (Fed. Cl. Spec. Mstr. Sep. 24, 2008) (describing the Comenge article as “basically a protest against the administration of the hepatitis B vaccine”). To be sure, a hypothesis should not be rejected solely because it is new. Bubb, 2005 WL 1025707, at *23. However, a

⁷⁸ Because Ms. Elson submitted a manuscript version of the Waisbren article, this decision cites to pdf numbering.

⁷⁹ When Dr. Tornatore was asked whether the Waisbren paper was published, he responded “I think it’s just a manuscript. I’m not sure that it’s ever been peer-reviewed.” Tr. at 260. However, the list of citations in Dr. Tornatore’s report provides bibliographic information. See Exhibit 29 at 12 (item 11).

hypothesis without support is unlikely to be persuasive. Caves v. Sec’y of Health & Hum. Servs., 100 Fed. Cl. 119, 134 (2011) (“a scientific theory that lacks any empirical support will have limited persuasive force”), aff’d without opinion, 463 F. App’x 932 (Fed. Cir. 2012). As such, without any data, it is difficult to deem either the Comenge article or Waisbren article as meriting much evidentiary weight.

Dr. Tornatore appears to overstate the value of the articles that he has cited. The five articles Dr. Tornatore cited in his report regarding causation (exhibit 29, dated January 22, 2017) were published in 2005 (Oldstone), 1995 (Matsui), 2005 (Bogdanos), 2006 (Comenge and Girard), and 2008 (Waisbren). When asked whether any additional investigations were performed, Dr. Tornatore stated: “I don’t know if others have been, but I’m not sure why people would continue to look because, to be honest, once it’s been demonstrated, it’s very hard to get something published if it’s already – there’s data already out there. So people move on to other things.” Tr. at 255.

It is difficult to credit Dr. Tornatore’s oral testimony that a causal link between the hepatitis B vaccine and demyelination has been “demonstrated.” As mentioned, Waisbren recommends additional experiments. Exhibit 49 (Waisbren). Bogdanos states that the hepatitis B “vaccine’s possible role as a trigger ... of viral/self cross-reactivity through molecular mimicry must be further investigated.” Exhibit 48 at 223 (Bogdanos). Bogdanos also describes the issue as surrounded in “controversy.” Id. at 222. Oldstone, who co-conceived molecular mimicry as a theory, emphasized that is a hypothesis. Exhibit 47 at 13 (Oldstone). Dr. Tornatore did not present any evidence that any of these experiments have been performed.

These medical articles’ calls for additional investigation seem to resemble the Federal Circuit’s statement that a special master may require “additional evidence” regarding molecular mimicry. W.C., 704 F.3d at 1360. In looking for “additional evidence,” the undersigned is following the Federal Circuit’s opinion in W.C. This opinion constitutes a precedent that is binding. An analysis looking for “additional evidence” is also consistent with multiple (albeit not all) opinions from the Court of Federal Claims, which are persuasive (not binding) precedent. See Caves v. Sec’y of Health & Hum. Servs., 100 Fed. Cl. 119 (2011), aff’d sub nom., 463 F. App’x 932 (Fed. Cir. 2012); see also Duncan v. Sec’y of Health & Hum. Servs., 153 Fed. Cl. 642 (2021), Yalacki v. Sec’y of Health & Hum. Servs., 146 Fed. Cl. 80 (2019).

In looking for additional evidence, the undersigned is mindful that petitioners do not have to prove any aspect of their cases with certainty. But, even

at a lower level of proof, the evidence Ms. Elson has produced does not meet her burden. She has not presented evidence of sufficient quantity and quality to show that the hepatitis B vaccine can aggravate a demyelinating condition. See La Londe v. Sec’y of Health & Hum. Servs., 110 Fed. Cl. 184, 200 (2013) (“The special master did not require petitioner to provide conclusive evidence from the medical literature or proof of the proposed biological mechanisms. Instead, he quite properly required petitioner to carry her burden to bring forward a reliable medical or scientific explanation”), aff’d, 746 F.3d 1334, 1340 (Fed. Cir. 2014).

For these reasons, Ms. Elson has not met her burden. She has not shown that neuroborreliosis is an autoimmune demyelinating disease. And, she has also not shown that a hepatitis B vaccine can cause (or aggravate) demyelination. Due to the failure on this prong, the remaining aspects of this case are unnecessary. DePena v. Sec’y of Health & Hum. Servs., 133 Fed. Cl. 535, 549 (2017) (“a failure to satisfy one prong is fatal to the case”), aff’d without opinion, 730 F. App’x 938 (Fed. Cir. 2018).

E. Loving Prong 5

Ms. Elson’s lack of proof regarding a theory makes further evaluation superfluous. Holmes v. Sec’y of Health & Hum. Servs., 115 Fed. Cl. 469, 488 (Fed. Cl. 2014) (“the failure to establish a medical theory satisfying the first prong of Althen might well make the objection regarding the second prong academic”); see also Nussman v. Sec’y of Health & Hum. Servs., 83 Fed. Cl. 111, 121 (2008) (indicating that proof of a medical theory is analytically distinct from a showing that a vaccine caused an injury). Nevertheless, for the sake of completeness, the remaining elements are considered.

The fifth Loving prong corresponds to the second Althen prong. This element requires petitioners to demonstrate a “logical sequence of cause and effect,” connecting the vaccination with a significant aggravation. Unlike Loving prong 4 in which the primary evidence is not about the vaccinee, Loving prong 5 concerns what happened to the vaccinee after the vaccination. For Ms. Elson’s case, this difference is reflected in the quantity of evidence. In Loving prong 4, Ms. Elson primarily relied upon five articles from medical journals plus two pages of testimony from Dr. Tornatore. In contrast, for Loving prong 5, multiple medical records shed some light on Mr. Hodge’s health after the vaccination. Ms. Elson’s written and oral testimony about her son’s health are other forms of evidence to consider.

This section begins with Ms. Elson’s descriptions of Mr. Hodge’s conditions after receiving the vaccinations. It then discusses that Mr. Elson has not

established that 1) the hepatitis B vaccination induced demyelination caused a series of symptoms for Mr. Hodge and 2) Mr. Hodge exhibited neurologic issues, along with bodily problems and OCD, within a relevant time frame after the vaccination. It then proceeds with a discussion on how Mr. Hodge's treating doctors have not persuasively linked the vaccinations to his health deteriorating. Lastly, it concludes with a synopsis on the evidence, viewed in its entirety, does not persuasively support that the hepatitis B vaccine significantly worsened an underlying neuroborreliosis manifesting as OCD.

1. Ms. Elson's descriptions of Mr. Hodge's health after the vaccinations

From the range of potential health attributes in Mr. Hodge, Ms. Elson has focused on a few. Under the heading "Loving Prong 5/Althen Prong 2," Ms. Elson argues:

The drastic exacerbation of Jeremy's Lyme disease logically fits the theory posited by Dr. Tornatore detailed above. Before the vaccine, Jeremy's Lyme disease and Lyme-induced OCD were progressing slowly as is the normal course of such conditions. Jeremy had no emergency room visits and no neurological symptoms. Following the hepatitis B vaccination, . . . Jeremy experienced the onset of neurological problems and had at least three different ER visits within eight months The neurological symptoms, such as oscillopsia and dizziness, that Jeremy experienced shortly after his vaccination are common in demyelinating disorders and strongly suggest that he had an acute demyelinating event.

Pet'r's Posthear'g Br. at 58.

In an earlier portion of Ms. Elson's brief, she detailed other ways in which Mr. Hodge changed after the hepatitis B vaccination. *Id.* at 41-46. These symptoms were discussed during the oral argument. A summary of these characteristics is:

Problem	Existence Before Vaccination	Date of Earliest Report in a Medical Record after Vaccination	Notes
Hallucinations	No reports prior to vaccination. <u>See</u> Oral Arg. Tr. at 558	July 10, 2007. Exhibit 11 at 7-8; Oral Arg. Tr. 558-59.	Denied at Encino-Tarzana in Aug. 2006. Exhibit 4 at 12. Mr. Hodge was “able to admit to having auditory and visual hallucinations” on June 9, 2008. Exhibit 10 at 12.
Depression / panic attacks	On Mar. 17, 2006, Mr. Hodge often felt sad, down, or hopeless. Exhibit 5 at 5. A June 20, 2007 Providence St. Joseph’s record reports a diagnosis of depression three years earlier. Exhibit 65 at 5. But, Ms. Elson reported him generally happy. <u>See</u> Tr. at 146; <u>see also</u> Oral Arg. Tr. at 560.	The UCLA record from Nov. 3, 2006 reports Mr. Hodge had a history of mood swings, crying, suicidal, anger and rage. Exhibit 67 at 2. The triage registered nurse did not check off “suicidal ideation.” <u>Id.</u> at 4. He was depressed. <u>Id.</u> at 2; <u>but see id.</u> at 4 (depression not checked). While at Transitional Youth, on December 7, 2007, Mr. Hodge was having panic attacks 5-25 times per day. Exhibit 10 at 70.	The panic attacks arguably appear to coincide with Ms. Elson’s adjusting medications. Oral Arg. Tr. at 562.
Eye movements	Not described in any medical record.	Dr. Rodriguez noted “uncontrollable eye movement” on Apr. 25,	The retained experts disagreed whether the

Problem	Existence Before Vaccination	Date of Earliest Report in a Medical Record after Vaccination	Notes
		2006. Exhibit 5 at 3; Tr. at 149. A note from Valley Presbyterian Hospital from June 2, 2006 notes “eye movement troubles.” Exhibit 6 at 8.	eye movements are neurologic in origin.
Cognitive Decline	Ms. Elson’s affidavit said “toward the end of 2005 [Mr. Hodge] was on track to get his GED.” Exhibit 21. A June 20, 2007 Providence St. Joseph’s record reports a diagnosis of depression as well as OCD 3 years earlier. Exhibit 65 at 5.	West Valley Mental Health records on July 10, 2007 document Mr. Hodge’s cognitive state. Exhibit 11 at 2-8.	Mr. Hodge also reported problems with his memory at Transitional Youth in early 2008. While at Transitional Youth, Ms. Elson adjusted Mr. Hodge’s medications. Mr. Hodge reported problems with intellectual functioning to Dr. Dasher at UCLA.
Arthralgias, Myalgias, Paresthesia	Ms. Elson averred that before the vaccinations, Mr. Hodge engaged in a wide variety of physical activities. Exhibit 86 at 9-10.	Per affidavits, Mr. Hodge had stabbing pains in his spine, legs, and arms the same evening his received his March 17, 2006 vaccine. Exhibit 9 at 2. After his April 25, 2006 vaccine, Mr. Hodge’s health significantly	Dr. Rodriguez’s notes from the appointment during which the second dose was administered do not mention any complaints

Problem	Existence Before Vaccination	Date of Earliest Report in a Medical Record after Vaccination	Notes
		<p>declined. He complained of “horrible fatigue, numbness in his arms, and stiffness throughout his body.” <u>Id.</u>; Exhibit 86 at 14.</p> <p>Dr. Rodriguez noted a complaint of neck pain on April 25, 2006. Exhibit 5 at 3.</p> <p>At Valley Presbyterian Hospital on June 2, 2006, Mr. Hodge reports back pain. Exhibit 6 at 7.</p> <p>At Encino-Tarzana on August 23, 2006, Mr. Hodge said it is hard to feel his skin. Exhibit 4 at 4.</p> <p>At UCLA on November 3, 2006, there is a report that he has decreased sensation to his skin for seven to eight months. Exhibit 67 at 2.</p> <p>At Providence St. Joseph Medical Center, on June 20, 2007, back pain is reported. Exhibit 65 at 5.</p>	of joint or muscle pain, although “neck pain” is mentioned.
Obsessive-compulsive symptoms	During the appointment for the administration of the first vaccine on Mar. 17, 2006, Dr. Rodriguez	Transitional Youth in Nov. 2007. Exhibit 10 at 55-57.	

Problem	Existence Before Vaccination	Date of Earliest Report in a Medical Record after Vaccination	Notes
	noted a history of OCD but no additional details were provided.		

As mentioned, the attorneys' assessments of the different categories contribute to the information presented in the chart.

As depicted in the chart, some of the problems that began after the vaccination (such as hallucinations) started more than a year after the vaccination.⁸⁰ Other problems were problems that Mr. Hodge had before the vaccination and worsened more than a year after the vaccination. Examples include cognitive decline, panic attacks, and obsessive-compulsive symptoms. Problems that either started approximately one year after the vaccination or began worsening approximately one year after the vaccination can be linked to the vaccination only if they were part of an overall pattern.

Dr. Tornatore asserted that these various problems constitute a logical sequence of cause and effect. According to Ms. Elson, "Dr. Tornatore is not alleging separate neurological injuries. Rather, he is saying they are part of the same disease process, i.e. part of Jeremy's neuroborreliosis, and more significantly, [they] represent a significant aggravation of his initial presentation of that condition – a relatively mild course of OCD – that was triggered by his Hepatitis B vaccinations." Pet'r's Posthear'g Br. at 30. Similarly, Ms. Elson explained that Dr. Tornatore's theory is that "the antigen in the hepatitis B vaccination triggered, most likely via molecular mimicry, an immune response characterized by autoimmune inflammation that ultimately resulted in autoimmune demyelination.

⁸⁰ Ms. Elson contended that Mr. Hodge began experiencing severe hallucinations during the summer of 2006. Exhibit 21 at 2. Dr. Baca's medical records from 2006 note Mr. Hodge denied any hallucinations. Exhibit 4 at 12. When asked about Dr. Baca's notation that Mr. Hodge denied hallucinations, Ms. Elson indicated that she probably stepped in, but the doctors ignored her complaint. Tr. at 215-16. According to Dr. Tornatore, a report of hallucinations constitutes a medical emergency. Tr. at 279-80. Thus, it seems unlikely that Dr. Baca would have ignored a report of hallucinations that came from Mr. Hodge or his mother. Cf. Tr. at 280, 404 (Dr. Tornatore and Dr. Venkatesan both discussing how doctors solicit histories from or about potentially delusional patients). Thus, Ms. Elson's testimony regarding hallucinations in the summer 2006 is not credited. It seems likely that a concerned and loving parent would take a child suffering from hallucinations for medical care as Ms. Elson did in the summer of 2007.

Jeremy experienced a host of neurological and psychiatric symptoms and his Lyme-induced OCD exacerbated to a point where he could no longer care for himself.” *Id.* at 48. Ms. Elson described her theory as one in which “external triggers, specifically the hepatitis B vaccination, can cause an inflammatory cascade significantly aggravating Lyme disease resulting in a broad range of neurological symptoms.” *Id.* at 55. The Secretary’s understanding is in accord: “the theory offered by petitioner’s expert involves a claim of significant aggravation of neuroborreliosis via a demyelinating event that was the result of molecular mimicry.” Resp’t’s Posthear’g Br. at 60.

2. Ms. Elson has not established a series of problems caused by a hepatitis B vaccination induced demyelination

It bears repeating that Dr. Tornatore’s theory posits that the hepatitis B vaccination caused demyelination. Ms. Elson asserts: “Petitioner’s expert puts forth the concept of molecular mimicry as the underlying mechanism resulting in Jeremy’s autoimmune demyelination.” Pet’r’s Posthear’g Br. at 52. The demyelination is something that, according to Ms. Elson and Dr. Tornatore, the hepatitis B vaccination caused. The demyelination allegedly differentiates Mr. Hodge’s pre-vaccination condition from his post-vaccination. *See id.* at 51 (“Jeremy’s neuroborreliosis drastically accelerated following the administration of the hepatitis B vaccination which led to an autoimmune demyelinating event”). Thus, it would seem to follow that the harmful consequences should be linked to demyelination.

The evidence about demyelination is limited both temporally and anatomically. In terms of timing, Mr. Hodge’s first MRI was performed in May 2009 (approximately three years after the vaccination). Exhibit 2. Without an MRI performed around the time of the vaccination, opinions about the state of Mr. Hodge’s myelin lack reliability. *See* Tr. 62, 78, 243-45, 373, 435. Dr. Tornatore even testified that he cannot, based on the 2009 MRI, say whether Mr. Hodge had a demyelinating event in March or April of 2006. Tr. at 243. The undersigned declines to assume that Mr. Hodge suffered from demyelination in 2006 because he suffered from demyelination in 2009.

Moreover, as discussed below, the August 11, 2009 MRI detected problems in the corpus callosum. Exhibit 7.1 at 65. If, for the sake of argument, it is assumed that problems in the corpus callosum can manifest as worsening OCD symptoms, then a problem with timing still exists. After the vaccination, Mr. Hodge’s OCD symptoms were first reported as worsening in November 2007 when Mr. Hodge was being treated at Transitional Youth. Exhibit 10 at 55. During oral argument, when asked to identify the earliest record reflecting a worsening in

OCD, Ms. Elson's attorney cited this record. Oral Arg. Tr. at 578-79. Between, on the one hand, the vaccinations in March and April 2006 and, on the other hand, the treatment at Transitional Youth, Mr. Hodge visited other medical facilities. However, records from these appointments document OCD but do not describe a worsening of OCD symptoms. See Exhibit 6 at 7 (Valley Presbyterian on June 2, 2006), Exhibit 4 at 4 (Encino Tarzana on August 23, 2006), Exhibit 67 at 2 (UCLA on November 3, 2006), Exhibit 65 at 2 (Providence St. Joseph's on June 20, 2007). Dr. Tornatore has not persuasively explained why it is logical to conclude that the March or April 2006 hepatitis B vaccinations would cause demyelination that leads to symptoms of that demyelination first documented more than one year later. Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355-56 (Fed. Cir. 2006).

Besides timing, the August 2009 MRI also presents a challenge to Mr. Hodge's theory of the case due to its anatomy. This MRI revealed problems in his corpus callosum. Exhibit 7.1 at 65. Relying upon the Saito and Li studies, Dr. Tornatore opined that deficits in the corpus callosum contribute to OCD. Exhibit 29 at 9; Tr. at 237; see also Pet'r's Posthear'g Reply at 20 ("The corpus callosum is a frequent target of autoimmune demyelination and a distinctly abnormal MRI showing the presence of multiple demyelinating lesions involving the corpus callosum, as was the case for Jeremy, can explain the onset of OCD"). While not persuasive, Dr. Tornatore's opinion that OCD might track to the corpus callosum might have some plausibility. See Section VI.B. (discussing Saito).

This evidence potentially connecting demyelination to one symptom that Mr. Hodge experienced (OCD) stands in contrast to the other symptoms that Mr. Hodge experienced. Dr. Tornatore has not presented any even plausible testimony that demyelination in the corpus callosum can cause eye problems, myalgias, depression, cognitive decline, etc. See Pet'r's Posthear'g Br. at 30 ("Dr. Tornatore testified that the location of the changes in the MRI, i.e. the corpus callosum fits the OCD pattern in the literature"). At one point, Dr. Tornatore was asked about whether the MRI tracks to the ocular problem and Dr. Tornatore initially responded: "I was not asked specifically about that, you know. Here, we're getting into an area that I was not asked about." Tr. at 73.⁸¹ Dr. Venkatesan explained that the brainstem contributes to the stability of eye movements. Tr. at 443-44.

⁸¹Upon further discussion, Dr. Tornatore stated: "His MRI shows multiple areas of inflammation. Could some of those areas lead to these eye motor issues? Absolutely, right? And they could also pose other symptoms." Tr. at 75. However, the undersigned declines to credit this testimony in part because of Dr. Tornatore's demeanor in responding to this line of questioning.

The May 19, 2009 MRI revealed an “unremarkable brainstem.” Exhibit 2 at 1-2. Any contention that Mr. Hodge had demyelination in areas of his brain responsible for eye problems, myalgias, depression, cognitive decline would not be based upon persuasive evidence.

3. Ms. Elson has not established that Mr. Hodge established neurologic problems within a relevant time after the vaccination.

As discussed in more detail below in section F, the experts agreed that if the hepatitis B vaccine were to cause an adverse reaction, then the manifestation of the adverse reaction would appear within six weeks (42 days). Exhibit 29 at 10,⁸² Exhibit E at 5. The question becomes: has Ms. Elson met her burden of establishing a logical sequence of events showing the vaccination worsened Mr. Hodge’s condition within this time?

Ms. Elson’s evidence on this point is based upon the following chronology found in the medical records:

Date	Event	Cite	Elapsed Days
3/17/2006	Mr. Hodge receives the first dose of the hepatitis B vaccine and the hepatitis A vaccine.	Exhibit 5 at 2,7	0
4/25/2006	Uncontrollable eye movement, neck pain, facial pressure, and itchiness is reported to Dr. Rodriguez. Mr. Hodge receives the second dose of the hepatitis B vaccine.	Exhibit 5 at 3	41
6/2/2006	At Valley Presbyterian, the chief complaint is “Dizzy / Eye movement disturbances” Also, “back pain, joint + muscle aches and fatigue since receiving Hep B & A vaccinations 4 [months] ago.”	Exhibit 6 at 7	38

Of these problems, Dr. Tornatore and Ms. Elson focus upon the eye movement and the dizziness. See Tr. at 27, Pet’r’s Posthear’g Br. at 58 (stating the “neurologic symptoms, such as oscillopsia and dizziness, that Jeremy experienced shortly after his vaccination are common in demyelinating disorders and strongly suggest that he had an acute demyelinating event” and citing Dr. Tornatore’s report, exhibit 29 at 10); Pet’r’s Posthear’g Reply at 11 (stating “Jeremy’s eye

⁸² Dr. Tornatore suggests that an increased risk of developing a neurologic problem due to a vaccination might extend to 9 or 10 weeks. Exhibit 29 at 10.

movement disorder/dizziness was a symptom of neurological manifestation”). Thus, the eye movement disorder and the dizziness are examined extensively below. However, to demonstrate that all possible claims have been considered, there is also an analysis of bodily problems and OCD. Each of the four problems (eye movement disorder, dizziness, body problems, and OCD) are discussed separately. For each of the four problems, there are summaries of the medical records, Ms. Elson’s written testimony, Ms. Elson’s oral testimony, and the expert commentary. Each part ends with an assessment.

a) Eye Movement Disorder

(1) Medical Records

In the April 25, 2006 appointment with Dr. Rodriguez, a subjective complaint was “uncontrollable eye movement.” Exhibit 5 at 3. This medical record does not contain any additional legible information about the nature, frequency, or duration of the uncontrollable eye movement. See id.

At the Valley Presbyterian Hospital, the chief complaint was “Dizzy / Eye movement disturbances.” Exhibit 6.1 at 7. Mr. Hodge underwent a vertical / horizontal nystagmus test and the result was negative. Id. A neurologic examination was within normal limits. Id. Mr. Hodge also underwent a CT brain scan, which was normal. Id. at 4, 10. Someone diagnosed Mr. Hodge with “neurological problems.” Id. at 2.

The parties have not identified other medical records in which Mr. Hodge was noted as having eye problems.⁸³ For example, when Mr. Hodge visited Encino–Tarzana in August 2006, the review of system stated that Mr. Hodge “denies any eye pain or discharge.” Exhibit 4 at 12; See Tr. at 86, 308. On examination, Mr. Hodge’s “extraocular muscles [were] intact.” Exhibit 4 at 13. The experts did not identify other medical records with an eye problem. Tr. at 85 (Dr. Tornatore), Tr. at 378 (Dr. Venkatesan). The lack of documentation tends to imply (but may not always establish) that Mr. Hodge was not having eye trouble after August 2006. See Bull v. Sec’y of Health & Hum. Servs., 156 Fed. Cl. 329, 337 (2021) (denying motion for review and ruling that a special master’s finding that a petitioner did not suffer from brachial neuritis when the contemporaneously created medical records did not show evidence of muscle weakness or wasting).

⁸³ The parties note that Mr. Hodge’s “eye contact was erratic” when he went to West Valley Mental Health in July 2007. Pet’r’s Posthear’g Br. at 11, citing Exhibit 11 at 2-8, Resp’t’s Posthear’g Br. at 12, citing Exhibit 11 at 7. However, eye contact differs from eye movement.

Moreover, when tested at an ophthalmology clinic years later, there was “[no] clinical evidence of optic nerve involvement [for both eyes].” Exhibit 7.1 at 9 (Nov. 13, 2009).

(2) Ms. Elson’s Written Testimony

In her first affidavit, Ms. Elson discussed Mr. Hodge’s health in March, April, and June 2006, corresponding to the appointments with Dr. Rodriguez and the visit to the Valley Presbyterian Hospital Emergency Room. Exhibit 9 at 2. However, she did not discuss her son’s eye movement problems. See Exhibit 9 (filed on Jan. 14, 2011).

In her second affidavit, Ms. Elson stated that after the vaccination in March 2006, Mr. Hodge “deteriorated rapidly. He went to the emergency room within a week. . . . His eyes were jittery and moving all over the place. That didn’t stop for the next year. He had to drop out of school.” Exhibit 19 (filed on Oct. 1, 2014) at 1.⁸⁴

In her third affidavit⁸⁵, Ms. Elson again wrote about Mr. Hodge’s condition after receiving the April 2006 vaccine. This chronology suggested that Mr. Hodge’s eye fluttering was in the summer of 2006. Exhibit 21 (filed on Oct. 16, 2015) at 1.

In the fifth affidavit, Ms. Elson also discussed Mr. Hodge’s condition. Starting with the March 17, 2006 vaccinations, Ms. Elson stated “After a while, he also developed these weird eye movements that he couldn’t control.” Exhibit 71 (filed on Nov. 26, 2018) at 3.

In the sixth and final affidavit, Ms. Elson maintained that after the first vaccination, other than OCD and being somewhat depressed, his “mental health was still pretty normal after the first vaccine.” Exhibit 86 (filed on Feb. 3, 2021) at

⁸⁴ No medical record corroborates Ms. Elson’s statement that Mr. Hodge went to an emergency room within one week of the March 2006 vaccination. In fact, at the hearing when Ms. Elson was asked whether she took Mr. Hodge to the doctor for any of the symptoms he experienced after the March 2006 vaccine, she responded: “Not at that time. It didn’t seem serious enough. We ended up at Dr. Rodriguez’s again later on [at the April 25, 2006 visit.]” Tr. at 149. However, Mr. Hodge went to an emergency room approximately one *month* after the second hepatitis B vaccination in April 2006.

Similarly, it appears that Mr. Hodge stopped his schooling before he was vaccinated. See Second Order and Opinion, 164 Fed. Cl. 633, 647 (2023).

⁸⁵ Ms. Elson titled the affidavit, filed on December 4, 2015, as the “third affidavit.” Exhibit 26. However, that affidavit is actually the fourth affidavit that Ms. Elson filed.

13. Physically, after the first vaccination, Mr. Hodge “experienced headaches and shooting pains up and down his back, and numbness in his arms.” Id.

After the second vaccine, “he couldn’t feel his arms, legs, and skin” and “he experienced severe rapid eye movement.” Id. Although she could not recall specifically when the uncontrollable eye movements began, she stated she knows it “got really bad” after the second vaccine. Id. at 14. “[I]t was constant and progressively worse for at least a year.” Id. “All the doctors that saw Jeremy saw it after Noble Community Clinic.” Id. Ms. Elson further averred that Mr. Hodge was having unusual eye movements in the days before they visited the emergency room at Encino-Tarzana. Exhibit 86 at 19.

(3) Ms. Elson’s Oral Testimony

Ms. Elson testified during the hearing held on June 14, 2021. With respect to the abnormal eye movements, Ms. Elson stated that they started after the March 17, 2006 vaccination. Tr. at 149. She did not bring Mr. Hodge for medical care immediately because the problems “didn’t seem serious enough.” Id.; accord Tr. at 176.

Ms. Elson stated that in the follow-up appointment with Dr. Rodriguez, Mr. Hodge and she told him about the eye fluttering and other problems. However, according to Ms. Elson, Dr. Rodriguez appeared unconcerned. Tr. at 149. After the second vaccination, Mr. Hodge became much, much worse. His eyes “went to absolute uncontrollable moving, even while he was sleeping.” Tr. at 151.

On cross-examination, Ms. Elson testified that after the second vaccination, everybody saw Mr. Hodge’s eye movements, and doctors noted that his eyes were jiggling up and down, though she was not certain if they were documented in all his medical records. Id. at 181. The eye movements were mild after the first vaccination but became very intense after the second vaccination. Id. at 182. Ms. Elson stated that after the second vaccination, she had no idea about Mr. Hodge’s Lyme disease. Id. at 189.

(4) Summary of Expert Commentary

(a) Dr. Tornatore

In Dr. Tornatore’s view, the eye movement that Mr. Hodge experienced were examples of oscillopsia. Exhibit 29 at 10, Tr. at 63. “Oscillopsia” means “a symptom in which objects appear to wiggle, jerk, or move back and forth; it sometimes accompanies nystagmus.” Dorland’s at 1324.

Dr. Tornatore stated that oscillopsia may be intermittent and parents might not recognize its importance. Tr. at 68-69. Dr. Tornatore appeared to rely upon Ms. Elson's assertion via her sixth affidavit that after the second vaccination, Mr. Hodge's eye movements were "constant and progressively worse for a year . . . nonstop movement up and down." Id. at 70; accord Tr. at 27 (Dr. Tornatore: the uncontrollable eye movements are "very, very profound").

As for the etiology of the eye movement disorders, Dr. Tornatore stated that "uncontrollable eye movements where the eyes are moving around [are] always neurologic." Id. at 80. The portion of the nervous system that is impaired is the central nervous system. Id. at 241. In support of his opinion that uncontrollable eye movements originate in the nervous system, Dr. Tornatore pointed out that Dr. Rodriguez, after learning about Mr. Hodge's eye problems, referred him to a neurologist, not a psychiatrist. Id. at 77, 460-61. Dr. Tornatore further specified that oscillopsia is associated with demyelinating conditions. Id. at 63. However, Dr. Tornatore conceded that the medical records in which Mr. Hodge was reported to have eye troubles do not show that any treating doctor considered demyelination. Tr. at 244.

With respect to the June 2006 visit to Valley Presbyterian Hospital, the normal CT scan of Mr. Hodge's brain did not rule out a neurologic problem because a CT scan may not detect subtle changes. Tr. at 312. Dr. Tornatore recognized that the doctors did not detect horizontal or vertical nystagmus. Tr. at 76. Dr. Tornatore stated the negative nystagmus result was "intriguing." Tr. at 310.

(b) Dr. Venkatesan

Dr. Venkatesan recognized that there was a complaint about abnormal eye movement on April 25, 2006 and again on June 2, 2006. Tr. at 371. Dr. Venkatesan was not confident about Dr. Tornatore's characterization of the symptoms as "oscillopsia." Dr. Venkatesan did not know if Mr. Hodge experienced a "sensation of bouncing around of vision or not." Id. at 372.

For the cause of the abnormal eye movement, Dr. Venkatesan was uncertain. He stated oscillopsia "can be a neurologic symptom, but it can also be a psychiatric symptom." Id. at 394, accord Tr. at 432. Dr. Venkatesan stated there is nothing in the medical records that the eye movements are "definitively attributable to neurological problems." Id. at 371. Dr. Venkatesan noted that he did not have "enough evidence to conclude that [the uncontrolled eye movements] are neurologic and that there are multiple other possibilities." Id. at 433. Dr. Venkatesan did not attribute much significance to Dr. Rodriguez's referral to a

neurologist because “the recommendation to see a neurologist or even a referral doesn’t necessarily mean that there is a neurologic problem.” Id. at 392.

Like Dr. Tornatore, Dr. Venkatesan recognized that a doctor from Valley Presbyterian Hospital did not detect any nystagmus. Tr. at 371. Dr. Venkatesan agreed with Dr. Tornatore that a CT scan would not show an inflammatory process. Tr. at 434.

(5) Assessment

As a preliminary matter, the reliability of the evidence must be assessed because special masters may rely upon only “reliable evidence.” Vaccine Rule 8(b). The reliable information about Mr. Hodge’s eye movement is limited. The reliable evidence consists of Dr. Rodriguez’s April 25, 2006 note, which memorialized a subjective complaint of “uncontrollable eye movement,” and the June 2, 2006 record from Valley Presbyterian, which documented a complaint of “Dizzy / Eye movement disturbances.” Exhibit 5 at 3; Exhibit 6 at 7. Medical personnel did not memorialize any notations that they observed the unusual eye movements.⁸⁶ See Resp’t’s Posthear’g Br. at 49 (noting the “records provide very little detail about these symptoms, such as a description of his vision (blurring, jumpy, jittery, etc.), what his eyes were doing during these ‘disturbances’ (still shaking, moving in any direction, etc.), whether [the] movement of his head affected his vision, how often the problem happened, how long it lasted, and whether it was associated with dizziness”).

The undersigned declines to credit some of Ms. Elson’s testimony about eye problems for several reasons. See LaLonde v. Sec’y of Health & Hum. Servs., 110 Fed. Cl. 184, 204 (2013) (indicating that when a special master rejects testimony, the special master must provide a basis), aff’d on non-relevant grounds, 746 F.3d 1334 (Fed. Cir. 2014). First, the first affidavit was prepared in 2011, which was more than four years after the 2006 vaccination. The passage of so many years dulls a person’s memory. Velchek v. Sec’y of Health & Hum. Servs., No. 02-1479V, 2005 WL 2847451, at *17 (Fed. Cl. Oct. 28, 2005).

Second, the testimony is inconsistent with respect to when the eye movements began. See Exhibit 19 (second affidavit, filed Oct. 1, 2014) (indicating that Mr. Hodge went to an emergency room for his eye movement problem within one week of his March 2006 vaccinations), Exhibit 21 (third affidavit, filed Oct.

⁸⁶ The lack of observation does not mean that Mr. Hodge was not having unusual eye movements at other times. He could have been experiencing abnormal eye movements intermittently. Tr. at 68.

16, 2015) (suggesting the eye trouble started in summer 2006), Exhibit 86 (sixth affidavit, filed Feb. 3, 2021) (indicating that the really bad eye problems started after the April 2006 vaccination).

Third, Ms. Elson seems to exaggerate Mr. Hodge's eye problems. Exaggerations may reduce a person's reliability. See Heath v. Sec'y of Health & Hum. Servs., No. 08-86V, 2011 WL 4433646, at *5 (Fed. Cl. Spec. Mstr. Aug. 25, 2011) (declining to credit the testimony of a fact witness due, in part, to "a tendency to exaggerate"); Watson v. Sec'y of Health & Hum. Servs., No. 91-1354V, 1992 WL 42927, at *6 (Cl. Ct. Spec. Mstr. Feb. 18, 1992) (declining to credit testimony of a vaccinee's mother when the special master found "her susceptible to exaggeration, and really unsure about exactly what happened when"). By her sixth affidavit, which was filed at the undersigned's direction more than 14 years after the 2006 vaccinations and after litigation had been pending for more than a decade, Ms. Elson asserted that the unusual eye movements were "constant," persisted for more than a year, and were seen by all doctors. Exhibit 86 at 14.

However, this account does not match the information found in the medical records created during these months. The Encino-Tarzana record from August 2006 is not consistent with Ms. Elson's account. When Ms. Elson and Mr. Hodge were at Encino-Tarzana, the review of symptoms indicates an affirmative statement that Mr. Hodge "denies any eye pain." Exhibit 4 at 12. Further, the doctor's examination indicated that Mr. Hodge's extraocular muscles were intact. Id. at 13.

If Mr. Hodge were experiencing constant and progressive problems with his eyes, then the doctor at Encino-Tarzana would have noted them. See Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). Consequently, with respect to some details about Mr. Hodge's eye problems, Ms. Elson's testimony is not a reliable source of information. See Tr. at 314 (Dr. Tornatore recognizing that reconciling Ms. Elson's affidavits is challenging).

Nevertheless, the two medical records listed above (Dr. Rodriguez's April 26, 2006 note and the Valley Presbyterian record from June 2, 2006) are reliable sources that Mr. Hodge was having eye problems, even if those records contain little information about them. Similarly, Ms. Elson's general account that Mr. Hodge was having eye problems is also accepted as reliable due to a consistency

with these medical records. See Exhibit 71. From the meager information in these records, Dr. Tornatore opines that Mr. Hodge was having neurologic problems.⁸⁷

Although Dr. Tornatore's opinion that Mr. Hodge's eye movements were neurologic is plausible, his opinion on this point does not rise to the level of more likely than not. Dr. Tornatore's characterization of the eye movements as a form of "oscillopsia" seems to stretch the evidence. Oscillopsia can be disorienting, making walking difficult. Tr. at 69. However, in the medical records that contain the reports of abnormal eye movements, there are not complaints about walking and Ms. Elson did not recall Mr. Hodge having problems walking. Exhibit 5 at 3; Exhibit 6.1 at 7, Exhibit 86 at 11, Tr. at 177. Furthermore, oscillopsia can accompany nystagmus. Dorland's at 1324. But, the single test for nystagmus was negative. Neither of the doctors who had the benefit of a personal observation of Mr. Hodge while treating him used this terminology in their notes. See Exhibit 5 at 3; Exhibit 6.1 at 7.⁸⁸ This lack of diagnosis tends to show that Mr. Hodge was not suffering from oscillopsia. A treating doctor's evaluation merits deference, although a report from a treating doctor is rebuttable. Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 706, 745 n. 67 (2009). Further, the complaints of unusual eye movements appear not to match the literal definition of "oscillopsia," which addresses changes in vision. See Tr. at 371.

Dr. Tornatore's insistence that eye problems are "always" neurologic (Tr. at 80) also seems to be an overstatement. Dr. Rodriguez's referral of Mr. Hodge to a neurologist does not mean that the problem is neurologic because, as Dr. Venkatesan explained, neurologists are sometimes referred patients who do not have a neurologic problem. See Tr. at 392. It is certainly reasonable to assert that eye problems are sometimes neurologic. Tr. at 373. However, Dr. Venkatesan

⁸⁷ In his oral testimony, Dr. Tornatore appeared to rely upon Ms. Elson's testimony that the eye problems were "constant and progressively worse for a year." Tr. at 70. However, this detail does not underlie Dr. Tornatore's main opinion on this topic. See Exhibit 29 at 10 (discussing oscillopsia).

⁸⁸ The lack of diagnosis from treating doctors refers specifically to "oscillopsia." The Secretary appears to err in asserting that "No treating physician diagnosed Mr. Hodge with neurologic dysfunction or diagnosed him with any neurologic condition, let alone oscillopsia, when he presented with vision issues." Resp't's Posthear'g Br. at 61. Actually, from the admission notes from Valley Presbyterian in June 2006, one diagnosis was "Neurological Problems." Exhibit 6.1 at 2.

commented that eye problems can be psychiatric in origin as well. Tr. at 394, 433. Dr. Tornatore did not persuasively rebut this point.⁸⁹

b) Dizziness

(1) Medical Records

The chief complaint at Valley Presbyterian Hospital included “Dizzy/Eye movement disturbances.” Exhibit 6.1 at 7. The brain CT scan, as noted above, was negative. Id. at 10. At discharge, the doctor prescribed meclizine, a medication for treating dizziness. Id. at 6; see also Dorland’s at 1102 (defining meclizine).

At the Encino-Tarzana emergency room, Ms. Elson informed medical personnel that Mr. Hodge complained of “dizziness associated with generalized weakness.” Exhibit 4 at 12. It was reported that Mr. Hodge was not taking any prescription medications. Id. at 12. It appears that Dr. Baca did not perform a neurologic exam. See id. at 12. The discharge diagnosis was “Neuropathy, etiology uncertain.” Id. at 13.

In November 2006, when Mr. Hodge visited the emergency room at UCLA, dizziness was not reported as a chief complaint. See Exhibit 67 at 2. He reported not to be taking any medications. Id.

The parties’ briefs do not identify any medical records created after the August 2006 Encino-Tarzana medical record in which a complaint about dizziness was made. See Pet’r’s Posthear’g Br.; Resp’t’s Posthear’g Br.

(2) Ms. Elson’s Written Testimony

In her first affidavit, Ms. Elson did not use the term “dizziness.” See Exhibit 9. She stated that on the evening of the first vaccination, Mr. Hodge had, among other problems, “stabbing pains that felt like electric shocks up his spine, his legs, and his arms.” Id. at ¶ 14. Ms. Elson described the visit to the Valley Presbyterian Hospital without mentioning dizziness. Id. at ¶ 21.

Ms. Elson’s second affidavit did not describe “dizziness.” See Exhibit 19. Her third affidavit also does not use the term “dizziness,” although Ms. Elson describes a host of many unusual behaviors. See Exhibit 21. Her fourth affidavit, which is mistakenly titled “Third Affidavit,” was directed to another purpose. See Exhibit 26.

⁸⁹ Mr. Hodge was suffering from a psychiatric illness at this time. See Tr. at 375.

Ms. Elson's fifth affidavit was created when a hearing was anticipated. She averred that within days of the March 17, 2006 vaccination, Mr. Hodge "started having headaches, dizziness, shooting pains up and down his back, and numbness in his arms." Exhibit 71 at ¶ 15. Otherwise, Ms. Elson provided no details about the dizziness.

Ms. Elson's sixth affidavit was in response to questions the undersigned proposed. In response to a question about Mr. Hodge's health after the March 17, 2006 appointment, Ms. Elson stated that "within days Jeremy experienced headaches, dizziness, shooting pains up and down his back, and numbness in his arms. These symptoms continued to get worse and worse following the vaccine on April 25, 2006." Exhibit 86 at 14. When asked about the visit to Valley Presbyterian Hospital, Ms. Elson averred that Mr. Hodge's dizziness and/or balance issues was "constant, but it got a little better after a couple years." *Id.* at 17.

(3) Ms. Elson's Oral Testimony

In the hearing, Ms. Elson testified that before the hepatitis B vaccinations, Mr. Hodge did not experience dizziness. Tr. at 205. After the vaccinations, Mr. Hodge was "weak" and "dizzy." Tr. at 151.

(4) Summary of Expert Commentary

Dr. Tornatore and Dr. Venkatesan often blended their comments about dizziness with their comments about the unusual eye movements, which are discussed above. To recap, Dr. Tornatore opined that oscillopsia and dizziness are neurologic symptoms are common in neurologic disorders and "strongly suggest" that Mr. Hodge had an acute demyelinating event. Pet'r's Posthear'g Br. at 58, citing Exhibit 29 (Dr. Tornatore's report) at 10.

On the other hand, Dr. Venkatesan indicated that dizziness can be caused by factors not involving demyelination. Examples include: an inner ear disturbance, motion sickness, and medication side-effects. Exhibit H, cited in Resp't's Posthear'g Br. at 63. Based upon the limited information available, Dr. Venkatesan could not opine on a more likely than not basis whether Mr. Hodge's dizziness was neurologic. Tr. at 434.

(5) Assessment

Overall, there is simply little information about Mr. Hodge's dizziness. Two medical records (one from Valley Presbyterian and one from Encino-Tarzana) mention dizziness. Ms. Elson's affidavits are more-or-less in accord with them in

the sense that she avers that Mr. Hodge had dizziness but adds no meaningful details.

Taken as a whole, the evidence does not preponderate in favor of finding that two episodes of dizziness, which otherwise do not prominently appear in any medical records, mark an acute demyelinating event. Dr. Tornatore stated that he did not know the cause of the dizziness. Tr. at 85. Dr. Venkatesan was persuasive in explaining dizziness can be caused by factors other than demyelination.

c) Body Problems

A set of symptoms that were reported to be occurring in Mr. Hodge within two months of his vaccination can be categorized as “body problems.” This category includes various problems, such as myalgias, arthralgias, and paresthesias.

(1) Medical Records

Dr. Rodriguez’s March 17, 2006 notes do not indicate any concerns about Mr. Hodge’s physical wellbeing, except for allergic rhinitis and sinusitis. Exhibit 5 at 2.

The notes from the April 25, 2006 appointment include a complaint about “neck pain, facial pressure, and itchiness.” Exhibit 5 at 3. In the legible portions of Dr. Rodriguez’s notes, there is no indication of a significant problem associated with these symptoms.

On June 2, 2006, when Mr. Hodge went to Valley Presbyterian, the history of present illness included: “back pain, joint + muscle aches and fatigue since receiving Hep B & A vaccinations 4 [months] ago. Blood tests done = normal per mother.” Exhibit 6.1 at 7. The review of systems indicated problems with fatigue, nasal discharge, bone/joint pain, back pain, headaches, dizziness, and frontal room spins. *Id.* Impression notes listed “dizziness” and “arthralgias – myalgias s[tatus]/p[ost] Hepatitis vaccination.” *Id.* at 6. Mr. Hodge was discharged that day, with his condition “Improving” and “Good.” *Id.*

At Encino-Tarzana, there was a chief complaint about paresthesias. Exhibit 4 at 12. A note from August 22, 2006 memorialized that “[t]he patient state[d] these symptoms have been evident intermittently since receiving [the] hepatitis vaccine earlier this year. The mother also state[d] that she [was] concerned that the patient, her son, appears more jaundiced, and also complains of dizziness associated with generalized weakness.” *Id.* A record from August 23, 2006

indicates that Mr. Hodge stated, “it’s hard to feel my skin” and indicates his “mom state[d] it all started p[ost] Hepatitis vaccine.” Id. at 4.

The November 3, 2006 medical record from the UCLA emergency room indicates that the chief complaint was decreased sensation to skin for seven to eight months, as well as facial pain and inability to relax. Exhibit 67 at 2. Mr. Hodge left before a psych evaluation could be performed. Id. at 5. The impression when Mr. Hodge left was OCD and numbness. Id. at 3.

In the June 20, 2007 Providence Saint Joseph Medical Center record, Mr. Hodge was seen for “depression, numbness to both hands.” Exhibit 65 at 2. The chief complaint was “[Patient] has multiple psychological problems x ‘months’ [complains of] physical ‘pain.’ Sudden onset on & off x ‘months.’” Id. The history of present illness recounts his history of problems: “Mother states that over the last year, he has had numerous symptoms including headache and chest pain, his Adam’s apple appears to be large, shortness of breath, numbness and tingling in his extremities, weight loss, difficulty eating, back pain, and uncontrollable fits. She describes this and many numerous somatic complaints.” Id. at 5. Dr. Wells stated that he “advised the mother that [Mr. Hodge’s] symptoms appeared to be somatic signs of severe major depression and anxiety.” Id. at 6. Dr. Wells also “strongly advised the mother that she needs to follow up at one of the County Facilities if she is unable to follow up with a neurologist and [] told the mother that [his] suspicion is that the patient has somatization of his psychological problems.” Id.

Although created years after the vaccinations, other medical records contain histories in which it was reported that the vaccinations preceded episodes of pain. See, e.g. Exhibit 7 at 46 (Olive View on August 4, 2009: Mr. Hodge received his routine hepatitis B vaccine at age 18 ½ and that he experienced subsequent stabbing spinal and back pain, and at age 19, complained of arm, neck, back muscle and skin tightness with spasms of gradual onset, which were intermittent), Exhibit 14.4 at 441 (Dr. Dasher on October 22, 2009: “‘Fog in head, memory issues, joint pains + aches throughout body.’ x 4-5 yrs.”).

(2) Ms. Elson’s Written Testimony

In her series of affidavits, Ms. Elson frequently testified about Mr. Hodge’s bodily problems. In the first affidavit, Ms. Elson stated that in the evening of March 17, 2006, Mr. Hodge “became violently ill with chills followed by hot flashes and stabbing pains that felt like electric shocks up his spine, his legs, and his arms.” Exhibit 9 at ¶ 14. “Days past and he still felt tired, but his symptoms did not seem too alarming.” Id. at ¶ 17. After the April 25, 2006 vaccination, Mr.

Hodge “complained of horrible fatigue, numbness in his arms, and stiffness throughout his body. He was unable to concentrate for any length of time. He left school and has not returned to his studies.” Id. at ¶ 20. When Mr. Hodge went to Valley Presbyterian, he “complained of terrible body pain, along with stiffness and numbness in his arms, legs, chest, and face.” Id. at ¶ 21.

In the second affidavit, Ms. Elson attested that “He got very very ill within the month after the shot. He deteriorated rapidly. He went to the emergency room within a week. He had severe pain shooting up and down his spine. He was screaming in pain.” Exhibit 19 at 1.

The third affidavit, dated October 16, 2015, indicates that “A few days after the vaccine, [Mr. Hodge] started screaming that he couldn’t feel anything in his arms and his legs.” Exhibit 21 at 1.

In the fifth affidavit, Ms. Elson stated that “Within days [of the March 17, 2006 vaccinations], [Mr. Hodge] “started having headaches, dizziness, shooting pains up and down his back, and numbness in his arms. After a while, he also developed these weird eye movements that he couldn’t control. He tired easily and could no longer play basketball, something that he had been enjoying prior to that.” Exhibit 71 at ¶ 15.

In the sixth affidavit, Ms. Elson stated that: “After the first shot, Jeremy experienced headaches and shooting pains up and down his back, and numbness in his arms. After the second shot, he couldn’t feel his arms, legs, and skin.” Exhibit 86 at 13; accord id. at 14.

When asked more details about the complaint of “neck pain” in the Valley Presbyterian medical record, Ms. Elson stated that: “After the second vaccine, Jeremy experienced severe spine and neck pain. He also lost sensation in lower legs, skin, and arms.” Id. at 15. The neck pain occurred: “All the time.” Id. “The shooting, stabbing pains lasted for a year and was constant. He experienced sporadic pain for years after.” Id. Because of the neck pain, Mr. Hodge “was unable to perform physical activities such as basketball.” Id.

In reference to the complaint of joint pain from Valley Presbyterian, Ms. Elson indicated that “All of his joints hurt. His knees, elbows, and fingers hurt, and he experienced stiffness.” Id. at 16. He had joint pain “every day . . . for about a year.” Id. at 17.

(3) Ms. Elson’s Oral Testimony

Ms. Elson testified that after the first shot on March 17, 2006, Mr. Hodge’s eyes started fluttering and he complained of spinal pain and itching. Tr. at 149.

Then, “[a]ll hell broke loose” after the second hepatitis vaccine. Id. at 150. She testified she requested an MRI “[e]very time” they went to an emergency room but was denied until 2009 because they had Medi-Cal / Medicaid. Id.

She testified his eye fluttering got worse after the second vaccine on April 25, 2006 and he experienced horrible pain, weakness, and dizziness. Id. at 151. Similarly, she alleged his personality changed and his ritualistic behavior became constant. Id. She stated she reported all these symptoms when she took him to the hospitals. Id.

(4) Summary of Expert Commentary

(a) The Experts’ Reports

The experts did not discuss these bodily problems extensively. For example, in Dr. Tornatore’s report presenting the opinion that the hepatitis B vaccination caused demyelination significantly aggravating Mr. Hodge’s Lyme-induced OCD, Dr. Tornatore stated that after the vaccinations, Mr. Hodge “experienced several neurologic symptoms, including dizziness and oscillopsia.” Exhibit 29 at 10. In the opinion portion of Dr. Tornatore’s report, Dr. Tornatore does not specifically assert that the hepatitis B vaccine caused Mr. Hodge’s paresthesias, myalgias, or arthralgias. See id. at 7-11.

In response to Dr. Tornatore’s report, Dr. Venkatesan appears to offer an explanation, other than the hepatitis B vaccine. Dr. Venkatesan asserted that: “Some of Mr. Hodge’s symptoms, including fatigue and joint issues, improved following initial Lyme treatment, suggesting that at least some of his symptoms were due to Lyme.” Exhibit E at 4. Dr. Venkatesan also proposes that a Jarisch-Herxheimer reaction could explain some of Mr. Hodge’s symptoms. Id. at 5.

A Jarisch-Herxheimer reaction was first described in the setting of syphilis. Id. (Syphilis is similar to Lyme disease because in both conditions a spirochete can invade the nervous system. Exhibit 29 (Dr. Tornatore’s report) at 8.) When the person is treated with a medication, like penicillin, the destruction of the bacteria release products that stimulate an inflammatory response. Exhibit E at 5. In Dr. Venkatesan’s opinion, Mr. Hodge’s receipt of amoxicillin on the date of his first vaccination could have caused some symptoms. Id.

In reply, Dr. Tornatore doubted that Mr. Hodge experienced a Jarisch-Herxheimer reaction. Exhibit 34 at 1. Dr. Tornatore would have expected that Mr. Hodge would have experienced systemic manifestations such as “rash, fever, myalgias, and arthralgias.” Id. In addition, the timing appeared not to fit. Id.

(b) The Experts' Oral Testimony

With reference to any constitutional symptoms that Mr. Hodge displayed in March and April 2006, Dr. Tornatore stated that they could be the result of an immune-mediated event. Tr. at 241. Dr. Tornatore indicated that neither Mr. Hodge's pre-existing Lyme disease nor a Jarisch-Herxheimer reaction would explain Mr. Hodge's condition after the vaccination. Dr. Tornatore stated that although an acute episode of Lyme disease could cause neck pain, Mr. Hodge had been suffering from Lyme disease for many years. Id. For the Jarisch-Herxheimer reaction, Dr. Tornatore stated that Mr. Hodge lacked typical manifestations, such as a fever or rash. Tr. at 36, 67. Dr. Tornatore further questioned whether amoxicillin could penetrate the central nervous system to access the spirochete. Tr. at 35-36, 67.

Dr. Tornatore noted that the June 2, 2016 medical records from Valley Presbyterian "associate arthralgias and myalgias with the hepatitis vaccinations, [s]o they are invoking some inflammatory event, not demyelinating [event]." Id. at 245. Dr. Tornatore assumed that "status post-hepatitis vaccination" meant those symptoms were "reported as occurring after the vaccine;" he could not state with certainty that they were the result of the hepatitis B vaccine. Id.

For the August 2006 treatment at Encino-Tarzana and November 2006 visit to UCLA, Dr. Tornatore commented that Mr. Hodge was reporting new neurologic symptoms---paresthesias, tingling, and difficulty feeling his skin. Tr. at 314-16. Dr. Tornatore reasoned that the vaccination caused a demyelinating inflammatory event that triggered Mr. Hodge's eye issues and the sensory issues. Id. at 317. Dr. Tornatore explained that Mr. Hodge could have inflammation that is persistent, starting in one area and then moving to another area. Id. at 333.

Dr. Venkatesan offered a different view. For Mr. Hodge's symptoms in April 2006, Dr. Venkatesan proposed that the amoxicillin might have entered the central nervous system, killing some of the spirochete and triggering a Jarisch-Herxheimer reaction. See id. at 379-80, 447 (limiting any Jarisch-Herxheimer reaction to April 2006). Dr. Venkatesan also suggested that numbness and tingling could be a manifestation of neuroLyme. Tr. at 396-97.

Relatively few questions were posed to Dr. Venkatesan about Mr. Hodge's treatment at Valley Presbyterian in which the treating doctor noted Mr. Hodge had developed arthralgias and myalgias after the hepatitis B vaccination. Regarding the headaches that were reported, Dr. Venkatesan indicated that "there are a number of things that could be going on that don't necessarily point to a specific process within the central nervous system." Tr. at 434. Similarly, Dr. Venkatesan

questioned the significance of a report of paresthesia in August 2006 because a sensory examination was not documented as abnormal. Tr. at 375.

(5) Assessment

To start, whether Ms. Elson is claiming that these various body problems are part of (the series of) adverse consequences to the hepatitis B vaccines is not entirely clear. As noted previously, Dr. Tornatore's primary report on causation did not assert that Mr. Hodge's body problems were a result of the vaccinations. See Exhibit 29 at 7-11. Before the hearing, in arguing why she met her burden on Loving prong five, Ms. Elson stated the "neurological symptoms, such as oscillopsia and dizziness, that [Mr. Hodge] experienced shortly after his vaccination are common in demyelinating disorders and strongly suggest that he had an acute demyelinating event." Pet'r's Prehear'g Br., filed Feb. 24, 2021 at 45. Ms. Elson did not argue that body problems in summer 2006 and onward are a direct or indirect consequence of the hepatitis B vaccine. See id. Overall, the lack of development regarding this potential theory tends to suggest that it is a relatively weak claim. Although Dr. Tornatore did not disclose an opinion that the hepatitis B vaccination caused bodily problems that were part of a series of problems in his reports, his testimony at least touched on these ideas. Tr. at 241, 314-17. Thus, they are examined below.

Next, the Jarisch-Herxheimer reaction appears to be a more likely explanation for at least some of Mr. Hodge's physical condition between the March and April vaccinations. Tr. at 446-47, exhibit E, tab 14 (Kadam). As explained above, a Jarisch-Herxheimer reaction happens when Lyme disease is treated. When the invading spirochete is destroyed, it releases residual particles that lead to an inflammatory reaction. Exhibit E at 5; exhibit E, tab 14 at e73 (Kadam). A Jarisch-Herxheimer reaction is associated with chills, fatigue, arthralgias, and myalgias that might last for up to 21 days. Exhibit E, tab 14 at e71 (Kadam).

Dr. Venkatesan offered this explanation in his report. Exhibit E at 5. Dr. Tornatore seemed to agree that a Jarisch-Herxheimer reaction could follow treatment for Lyme disease, although he questions whether amoxicillin could penetrate the nervous system. Tr. at 35, 67, see also Tr. at 380, 449-50 (Dr. Venkatesan's testimony about amoxicillin crossing the blood-brain barrier). Dr. Tornatore's primary point of disagreement was that Mr. Hodge did not experience constitutional symptoms of a Jarisch-Herxheimer reaction because he did not have a "fever, rash, headache, any of these other things that would suggest that there is a brisk immune response due to the splitting open of the spirochete." Id. at 36. However, Ms. Elson describes Mr. Hodge's condition the night of the first

vaccination as being “violently ill with chills followed by hot flashes.” Exhibit 9 ¶ 14. Ms. Elson thought Mr. Hodge “had caught the flu.” *Id.* at ¶ 15. Mr. Hodge “felt hot” for two days. *Id.* at ¶ 16. Dr. Tornatore appears to overlook this evidence from Ms. Elson.⁹⁰

Importantly, Mr. Hodge appears to have experienced similar problems at the end of 2009. On December 11, 2009, the infectious disease specialist, Dr. Mathisen, prescribed a different antibiotic, ceftriaxone. Exhibit 14 at 3. Within a week, Mr. Hodge developed a body rash and fevers. Exhibit 7.1 at 3, see also Exhibit 14 at 5. At discharge, the author indicated that Mr. Hodge’s skin rash was “a drug-induced rash secondary to ceftriaxone use and less likely other entities, including a Jarisch-Herxheimer reaction.” Exhibit 7.1 at 68. Within another month, in January 2010, Dr. Clough obtained a medical history that Mr. Hodge’s symptoms worsened two years ago when he simultaneously received amoxicillin and the hepatitis B vaccine. Exhibit 13 at 5. With respect to Mr. Hodge’s most recent hospitalization, Dr. Clough stated: “It is still not entirely clear whether he was actually having a reaction to ceftriaxone or whether he is reacting to treatment of the Lyme disease.” *Id.*⁹¹ Although the situations do not match perfectly, they seem to establish a pattern that some medications cause an unintended reaction in Mr. Hodge.⁹²

The presence of Lyme disease further complicates the assessment of the etiology for body pains in 2006. Dr. Tornatore stated a person who is infected with the bacteria “might have a rash or joint achiness or joint inflammation.” Tr. at 18. Dr. Tornatore also stated that the presence of Lyme disease manifesting as OCD shows that Mr. Hodge had inflammation in his nervous system before the vaccination. Tr. at 32-33, 44, 59-61. Dr. Tornatore emphasized that the

⁹⁰ Vagueness in Dr. Venkatesan’s first report may have contributed to Dr. Tornatore’s apparent oversight. Dr. Venkatesan’s initial report could be understood as proposing a Jarisch-Herxheimer reaction to explain Mr. Hodge’s symptoms in June 2006 when he went to Valley Presbyterian. See exhibit E at 5. But, in Dr. Venkatesan’s testimony, he narrowed his opinion regarding a Jarisch-Herxheimer reaction to April 2006, not June 2006. Tr. at 447.

⁹¹ The Secretary raised Dr. Clough’s commentary. Resp’t’s Posthear’g Br. at 50-51. Ms. Elson did not respond to the point about Dr. Clough. See Pet’r’s Posthear’g Reply.

⁹² Dr. Tornatore also discounted a Jarisch-Herxheimer reaction in 2006 because Mr. Hodge received amoxicillin in 2004 without any documented reaction. Tr. at 35, see also Exhibit 3.1 at 3. However, it is not clear that Mr. Hodge’s Lyme disease had progressed to neuroborreliosis in 2004.

inflammation in Lyme disease is independent of the spirochete. Tr. at 94-96, 101 (agreeing that “Lyme disease is an inflammatory infection driven disease”), 292.

While Dr. Tornatore opines that the inflammation from Lyme disease made Mr. Hodge “prone” to an adverse reaction, Tr. at 33, Dr. Tornatore has not explained why the hepatitis B vaccine contributed to his symptoms. As discussed above, Dr. Tornatore’s causal (or aggravating) theory is that the hepatitis B vaccination caused demyelination. See Section VI.A. above. Concededly, Dr. Tornatore mentioned that the vaccine caused a “demyelinating inflammatory event.” Tr. at 317. But, overall Dr. Tornatore has not persuasively shown (a) that the hepatitis B vaccine causes inflammation that leads to disease (see Tr. at 383-84 for Dr. Venkatesan’s testimony that this is possible) and (b) that any inflammation from the two doses of the hepatitis B vaccine more greatly contributed to inflammation derived from a multi-month untreated infection.⁹³

d) OCD

(1) Medical Records

The Valley Presbyterian records and records from Encino-Tarzana do not describe any worsening of OCD. See Exhibits 6 and 4.

During an emergency room visit on November 3, 2006, Mr. Hodge’s chief complaints were: 1) decreased sensation to the skin for the past 7 to 8 months, 2) facial pain and 3) inability to relax. Exhibit 32 at 27. He reported that he had depression, mood swings, crying, suicidal ideations, anger and rage. Id. His discharge impressions were OCD and numbness. Id. at 28. Dr. Tornatore did not persuasively indicate that these symptoms are symptoms of OCD.

The June 20, 2007 Providence St. Joseph medical record indicates Mr. Hodge “has multiple psychological problems” for an unspecified number of months. Exhibit 65 at 2. The doctor advised that Mr. Hodge appeared to have “somatic signs of severe major depression and anxiety.” Id. at 6.

The July 10, 2007 West Valley Mental Health Center report notes Mr. Hodge’s history of OCD and “2 years of tapping, touching, counting, stress with environment made it worse.” Exhibit 11 at 3. While Mr. Hodge was suffering from other mental health problems, this report does not list his OCD was worse because of the vaccinations.

⁹³ Dr. Venkatesan opined that no evidence showed that Mr. Hodge had inflammation. Tr. at 399.

On September 9, 2007, the medical history included “OCD problems” at West Hills. Exhibit 8.5 at 76. Ms. Elson informed Dr. Kuban that Mr. Hodge’s personality had changed “over the last eighteen months.” Id.

(2) Ms. Elson’s Written Testimony

In the first affidavit, filed on January 14, 2011, Ms. Elson did not discuss OCD symptoms or any ritualized behaviors. See Exhibit 9.

In the second affidavit, filed on October 1, 2014, Ms. Elson stated that Mr. Hodge began exhibiting “OCD hoarder symptoms” within a year of getting a bulls-eye rash on his leg and having flu-like symptoms after a camping trip. Exhibit 19 at 1.

In the third affidavit, filed on October 16, 2015, Ms. Elson wrote that Mr. Hodge’s OCD developed around age 16 and engaged in ritualistic behaviors but “they didn’t consume his entire life like they did for the next seven or eight years following the vaccine.” Exhibit 21 at 1. Ms. Elson explained that Mr. Hodge’s “OCD made him fall too far behind in school to keep up with ordinary classes,” so he opted to get a GED instead. Id. He was on track to get his GED at the end of 2005, but “his rituals, obsessions, and compulsions became so severe during the summer of 2006 that attending any classes whatsoever was a pipe dream . . . [and his] symptoms have since prevented him from returning to school.” Id.

In the fifth affidavit, filed on November 26, 2018, Ms. Elson stated that before the vaccinations, “[w]hile [Mr. Hodge] had OCD symptoms, they did not interfere with his daily life.” Exhibit 71 at ¶ 9. Mr. Hodge performed well in school and enjoyed “hiking, riding bikes, swimming, going to WWE wrestling events, shows, and even opera . . . [and] play[ed] video games with friends.” Id.

In the sixth affidavit, filed on February 3, 2021, Ms. Elson reported that Mr. Hodge was first diagnosed with OCD at Valley Care on Victory Boulevard sometime after April 30, 2003. Exhibit 86 at 12-13. Mr. Hodge engaged in various ritualistic behaviors, such as ritualistically turning the TV on and off, walking up and down the stairs numerous times, and turning the stove on and off. Id. at 13. Valley Care initially treated him with Prozac and eventually switched him over to Zoloft. Id. at 13. He was treated by Dr. Nasse for OCD from 2004 through March 17, 2006. Id. at 11.

At the Noble Community Clinic, Ms. Elson inquired if there was a program that Mr. Hodge could participate in for his OCD. Id. at 13. Ms. Elson recalled that on March 17, 2006, the first day of his vaccination, Mr. Hodge had OCD and was somewhat depressed, “but he was active and enjoying activities [and] [h]is mental

health was still pretty normal after the first vaccine.” Id. From June 3, 2006 to August 21, 2006, Ms. Elson stated that Mr. Hodge’s OCD “was still there, but the focus was on other problems, so OCD wasn’t at forefront of concerns. It seemed like it wasn’t as bad, but it came back with a vengeance later on.” Id. at 18.

At the Encino-Tarzana Regional Medical Center in August 2006, Ms. Elson discussed OCD with medical personnel but “[did not] recall mentioning that it had worsened.” Id. at 19.

At the UCLA Regional Medical Center on November 3, 2006, Ms. Elson stated that Mr. Hodge’s OCD “was about the same” as before, compared to his OCD when he went to Encino-Tarzana Regional Medical Center in August 2006. However, when asked to compare Mr. Hodge’s OCD when he went to West Valley to when he went to UCLA on November 3, 2006, Ms. Elson responded: “It was worse, along with everything else. It was more constant and intense and really aggravated him.” Id. at 24. At UCLA, Ms. Elson probably discussed OCD with medical personnel because “she normally brought it up” at medical appointments. Id. at 21.

(3) Ms. Elson’s Oral Testimony

Ms. Elson testified that, to her own recollection, Mr. Hodge began experiencing OCD symptoms at the age of 16. Tr. at 145. Mr. Hodge was diagnosed with OCD when he was 17 at Valley Care. Id. Though Mr. Hodge exhibited various ritualistic behaviors, such as turning on and off the faucet and light switch repeatedly, his OCD symptoms did not interfere with his life before his first Hepatitis B vaccine. Id. at 146. He lived a “very normal” life and Ms. Elson described him as an “active, happy person” who enjoyed “hanging around with friends,” playing basketball and video games, skateboarding, wrestling, as well as riding his bicycle. Id. However, he quit school in eleventh grade because his OCD symptoms “made him work a little slower because he would get caught up counting . . . [s]o he decided he wanted to take his GED instead.” Id.

According to Ms. Elson, Mr. Hodge’s OCD “literally went through the roof” and his “personality completely changed” after the vaccinations. Id. at 151. Ms. Elson testified that Mr. Hodge never returned to baseline in the intervening years since the vaccinations. Id. at 157-58.

When asked during cross-examination whether Mr. Hodge was seeing any other doctors for treatment for his OCD, Ms. Elson stated: “It’s kind of hard to remember. Everything is so –just such a blur now. I may have, about that time, gone to Dr. Nasse, but other than that, I’m sorry, I don’t remember.” Tr. at 161. Ms. Elson recalled in September 2004, Mr. Hodge was taking Adderall, prescribed

by Dr. Nasse, to help with his concentration. Id. at 162-63. Ms. Elson stated that Mr. Hodge had OCD during his tenth grade and some of the eleventh grade. Id. at 163.

(4) Expert Commentary

Dr. Tornatore emphasized that Mr. Hodge's OCD is connected to his Lyme disease. Tr. at 42. Dr. Tornatore opined that the imaging on the MRI showing a lesion in the corpus callosum made Mr. Hodge's OCD anatomic. Id. at 48-49, 121.

Dr. Venkatesan was reluctant to say that Mr. Hodge's OCD relapsed after the vaccination because of a lack of details. Tr. at 370. He also stated that OCD is associated with somatic complaints. Id. at 375.

(5) Assessment

Ms. Elson's claim is ultimately that the hepatitis B vaccines worsened Mr. Hodge's OCD. Pet'r's Posthear'g Br. at 48, 59. However, when viewed in isolation, a connection between the vaccinations and any worsening of OCD is not logical.

The main problem is that the worsening of Mr. Hodge's OCD occurred more than a year after the vaccinations. The medical records created in 2006 after the vaccination do not describe any change in Mr. Hodge's OCD. See Exhibit 86 at 18, see also Tr. at 152 (Ms. Elson's testimony that she reported all symptoms to Mr. Hodge's doctors). These records contrast with Ms. Elson's oral testimony that shortly after the second vaccination Mr. Hodge's "OCD went through the roof." Tr. at 151.

When asked to identify the earliest post-vaccination medical records showing a worsening of OCD, Ms. Elson's attorney cited a November 26, 2017 record from Transitional Youth. Oral Arg. Tr. at 578-79.

Preponderant evidence tends to show that the worsening of Mr. Hodge's OCD occurred many months after the vaccinations. If Mr. Hodge were as vulnerable to having his OCD worsen as Dr. Tornatore predicted, it would seem that the OCD would have worsened more quickly. Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1358 (Fed. Cir. 2006) ("If, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame").

4. Treating Doctors Have Not Persuasively Linked the Vaccinations to a Decline in Mr. Hodge's Health

With respect to the second Althen prong corresponding to the fifth Loving prong, the Federal Circuit has instructed special masters to consider carefully the views of a treating doctor. Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). Thus, the order for the submission of briefs before any adjudication directed the parties to discuss instances in which treating doctors commented upon the vaccination as potentially harming Mr. Hodge. Order, issued March 23, 2018, at 9.

From the host of doctors who have treated Mr. Hodge, the parties identify a few. Ms. Elson identified Dr. Mishra, Dr. Mathisen, Dr. Munoz, and an unidentified ophthalmologist. Pet'r's Prehear'g Br. at 34-35 (filed on June 28, 2018). After the hearing, Ms. Elson listed Dr. Mishra, Dr. Mathisen, Dr. Munoz, but not the ophthalmologist. Pet'r's Posthear'g Br. at 58-59, see also Pet'r's Reply Br. at 15, 21 (mentioning Dr. Munoz and Dr. Mathisen, respectively). The Secretary identifies doctors who treated Mr. Hodge in 2006. Resp't's Posthear'g Br. at 61-62. A chronological review of the doctors whom the parties identified starting with the earliest follows:

June 2, 2006 Valley Presbyterian: The doctor reached two impressions: "1. Dizziness" and "2. Arthralgias – Myalgias s/p [status post] Hepatitis Vaccination." Exhibit 6 at 6.

August 2006 Encino-Tarzana: Ms. Elson provided a history that "it all started [after] Hepatitis vaccine." Exhibit 4 at 4. Dr. Baca determined that Mr. Hodge could be managed on an outpatient basis and discharged him. Id. at 13. Dr. Baca's assessment did not comment, one way or the other, as to whether the hepatitis B vaccine affected Mr. Hodge adversely.

August 2009 UCLA Olive View: On August 4, 2009, Mr. Hodge and Ms. Elson visited the Olive View-UCLA facility for a neurology evaluation. The report is contained in two pages in the record. Exhibit 7.1 at 45-46. The chief complaint / history of present illness reads:

22 y/o [year old] M [male] referred for headaches from Mid Valley – Dr. Munoz. Pt was normal prior to age of 17, abrupt onset OCD-like behavior (counting, checking, etc.) over 1 month, then onset of a mental 'fogginess' / 'detachment from reality' of insidious onset that since waxed and waned with periods of 'normalcy.' By the age 19, mother states he has never been

back to baseline psych level --- always somewhat detached / weird.^[94] At age 18½ had routine hep B vaccine, then that night had stabbing spinal/back pain [with] neg CT head. . . . + tick exposure in Nor Cal [with] neighbor [with] Lyme Dz. Mother convinced [symptoms?] 2/2 Hep vaccine.

Id. at 46.

On the top of page 45, a resident whose name is illegible but might be “Plunkett” has written an assessment and plan. This assessment and plan summarizes, in three lines, Mr. Hodge’s medical history. The differential diagnosis includes: “MS, Lyme Dz, post vaccination demyelinating dz, other demyelinating dz.” Exhibit 7.1 at 45. In the bottom of the page, the attending neurologist (Shri Mishra) states Mr. Hodge’s history. It appears that Dr. Mishra (as opposed to the resident) did not state that Mr. Hodge might have “post vaccination demyelinating” disease. See id.

Ms. Elson identified a medical record appearing in the record as Exhibit 7 at 45 as one in which Dr. Mishra presented a “differential diagnosis of ‘post-vaccination demyelinating disorder.’” Pet’r’s Posthear’g Br. at 58. The document on that page contains handwritten statements made by two different professionals and Dr. Mishra did not include “post-vaccination demyelinating” disease in a differential diagnosis.⁹⁵ Ms. Elson further asserted that “Dr. Munoz, a treating neurologist, distinguishes [Mr. Hodge’s] pre-vaccination condition from his post-vaccination disorder.” Id. For this assertion, Ms. Elson cited exhibit 7 at 45. However, the history, which actually is on page 46, states that Dr. Munoz referred Mr. Hodge. The remaining history appears to be derived from Mr. Hodge and/or Ms. Elson.

December 11, 2009 Dr. Mathisen: The introduction of this report states that Mr. Hodge has “chronic neuropsychiatric syndrome,” including “obsessive-compulsive disorder.” Exhibit 14.1 at 3. Mr. Hodge also had a history of “possible Lyme disease 4-5 yrs.” Id. Dr. Mathisen’s assessment begins “#1: Neuropsychiatric disorder: Pt’s symptoms are compatible with chronic neurolyme as described in literature.” Id. Ms. Elson accurately quotes Dr. Mathisen’s report. Pet’r’s Posthear’g Br. at 58-59. However, Dr. Mathisen does not, in this record,

⁹⁴ “Weird” is somewhat illegible, but according to the Opinion and Order from March 7, 2023, the Court decodes “weird.” See Second Opinion and Order, 164 Fed. Cl. 633, 643.

⁹⁵ See Second Order and Opinion, 164 Fed. Cl. 633, 637 n.4 (2023) (ascribing an error in implying Dr. Mishra wrote the assessment).

memorialize Mr. Hodge's receipt of the hepatitis B vaccine. Dr. Mathisen does not comment whether the hepatitis B vaccination worsened Mr. Hodge's symptoms.

The parties did not identify any other medical records in which treating doctors commented upon any potential adverse effects of the hepatitis B vaccinations. See Pet'r's Posthear'g Br. at 58-59; Resp't's Posthear'g Br. at 61-62.

Overall, this collection of medical records does not weigh in favor of finding that the hepatitis B vaccinations harmed Mr. Hodge. These medical records generally present the doctor's memorialization of a history provided by Ms. Elson and/or Mr. Hodge. The presentation of a history differs from a doctor's diagnosis. See La Londe v. Sec'y of Health & Hum. Servs., 110 Fed. Cl. 184, 206 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014). Similarly, a doctor's recording that a vaccination occurred before an event (or an adverse health event developed after a vaccination) presents a sequence of events and a sequence of events is not the same as an expression of causation. Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d 1328, 1347-49 (Fed. Cir. 2010); Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1323 (Fed. Cir. 2010). Moreover, the Valley Presbyterian doctor's statement was made without the knowledge that Mr. Hodge suffered from Lyme disease. Incomplete and/or inaccurate information can diminish the evidentiary value of a report from a treating doctor. Schmidt v. Sec'y of Health & Hum. Servs., No. 17-1530V, 2021 WL 5226494, at *10 (Fed. Cl. Spec. Mstr. Oct. 7, 2021) ("[I]f an evaluation of the record reveals that a physician received inaccurate or incomplete information about a petitioner's medical history, the weight given to a statement or opinion from such a physician could be reduced.").

5. Synopsis regarding *Loving* Prong Five / *Althen* Prong Two

Overall, the evidence that the hepatitis B vaccine significantly worsened an underlying neuroborreliosis manifesting as OCD was neither logical nor persuasive. To a large extent, Ms. Elson's theory turns on the abnormal eye movements as neurologic. This proposition is far from fanciful, and another finder of fact could reasonably credit this idea. See Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357, 1368 (Fed. Cir. 2000). However, the undersigned declines to make this finding of fact. The reliable evidence about abnormal eye movements is contained in two medical records. Neither treating doctor to whom complaints were made diagnosed Mr. Hodge with a neurologic condition and the treating doctor at Valley Presbyterian conducted a nystagmus test and did not elicit any eye problems. The doctor at Encino-Tarzana recorded that Mr. Hodge did not report eye pain and an examination of his eyes showed that the extraocular muscles were intact. Ms. Elson has not identified any medical record stating that Mr. Hodge later experienced those abnormal eye movements.

Further, Dr. Tornatore did not persuasively link the series of problems to any demyelination/inflammation the hepatitis B vaccine caused (assuming the hepatitis B vaccine can cause these problems). In 2006, after the March vaccination, Mr. Hodge reported a series of problems including abnormal eye movement, neck pain, joint pain, muscle pain, decreased sensation in his skin, and changes in his mood. Dr. Tornatore has not persuasively explained how two doses of a vaccine, which does not contain any replicating components, can cause this diverse set of symptoms. Some of these symptoms lasted for a short time and did not appear in other medical records. Other symptoms began more than two months after the April vaccination. The supposition that the hepatitis B vaccine caused all these health problems before the hepatitis B vaccine caused a worsening OCD that, according to Ms. Elson's attorney, took place more than a year after the vaccination is not likely. Accordingly, Ms. Elson does not meet her burden on Loving prong 5/Althen prong 2.

F. Loving Prong 6

The sixth Loving prong derives from the third Althen prong. The timing prong actually contains two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and the onset of the disease (or aggravation) occurred in this period. Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013).

Here, Dr. Tornatore has proposed that the harmful reactions to the hepatitis B vaccine would primarily occur within the first five weeks after vaccination, although the period might extend to 10 weeks. Exhibit 29 at 10. Dr. Venkatesan agreed with that interval. Exhibit E at 5. Thus, Ms. Elson has established the first part of this element.

As for the second part of this element, Dr. Tornatore focused on "new and unique" "neurologic symptoms." Exhibit 29 at 10. In practice, these symptoms were alleged to have been uncontrollable eye movements. See Pet'r's Posthear'g Br. at 60. As discussed above, Ms. Elson has not presented preponderant evidence that the uncontrollable eye movements, which are mentioned in two medical records, must be neurologic in origin. See section VI.E.3.a. But, the abnormal eye movements were noted within the time for which an inference of causation is appropriate. See Exhibit E at 5.

Any finding that Mr. Hodge's health deteriorated shortly after the hepatitis B vaccinations does not necessarily mean that the hepatitis B vaccinations caused any worsening. Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144 (Fed. Cir.

1992) (“Temporal association is not sufficient, however, to establish causation in fact.”). Given the findings on Loving prong four and Loving prong five, further discussion of Loving prong six is not required.

The foregoing analysis covers the six Loving prongs. To recap, Ms. Elson has carried her burden with respect to the first three elements in that she has persuasively shown that Mr. Hodge’s current condition is worse than condition before he received the vaccinations in 2006. For the fourth prong, Ms. Elson’s case falters. She has not shown how a hepatitis B vaccine can aggravate (or cause) a demyelinating condition. Moreover, with respect to the fifth prong, Ms. Elson has not demonstrated a “logical sequence,” linking the vaccinations to a decline in Mr. Hodge’s health. Finally, if Ms. Elson had established prongs 4 and 5, she would have met her burden on prong six. But, she did not meet her burden on these prongs. Thus, she cannot be awarded compensation.

G. Alternative Causes: Pre-Existing Problems

Before the vaccinations, Mr. Hodge suffered from neuroborreliosis manifesting as OCD. Mr. Hodge has claimed that the hepatitis B vaccinations worsened his neuroborreliosis. However, as explained above, Mr. Hodge’s proof—particularly his proof of Loving prong 4 / Althen prong 1—is not persuasive. In other words, Ms. Elson has not established a *prima facie* case and the burden of proving a factor unrelated to the vaccinations caused Mr. Hodge’s health problems after the vaccinations has not shifted to the Secretary. LaLonde v. Sec’y of Health & Hum. Servs., 746 F.3d 1334, 1340 (Fed. Cir. 2014). Accordingly, the discussion of pre-existing problems is not necessary to this decision. But, the discussion is nonetheless included to ensure that all issues are presented.

This section begins with a discussion of the legal burden. It then provides an analysis of the evidence, specifically the evidence does not show the vaccinations exacerbated Mr. Hodge’s OCD. Lastly, it concludes with a discussion on the Secretary effectively disclaiming any argument that preponderant evidence shows that either Lyme disease, OCD, or both Lyme disease and OCD explain Mr. Hodge’s conditions.

1. Legal Burden

With respect to information about how neuroborreliosis and OCD normally progress, Ms. Elson recognizes that “Respondent can certainly present the evidence.” Oral Arg. Tr. at 600. Ms. Elson further recognizes that after the Secretary presents evidence about the natural course of any underlying disorder,

the special master “can consider it.” *Id.* The ensuing question, then, becomes in what part of the analysis may the special master consider it.

The Secretary raised the manifestations of Lyme disease and a potential Jarisch-Herxheimer reaction within a general argument that Ms. Elson did not meet her burden of proof regarding Loving prong 2. Resp’t’s Posthear’g Br. at 48-50. The Secretary maintained that “the Special Master can consider evidence of natural course of the condition as evidence against a finding of vaccine causation.” Oral Arg. Tr. at 602. The Secretary contended that “Stone and Doe 11 both indicate that the Special Master can consider evidence of other possible causes of the injury in determining whether petitioner[s] met their prima facie case.” *Id.*⁹⁶

In contrast, Ms. Elson argued that a Jarisch-Herxheimer reaction does not explain Mr. Hodge’s problems under the heading “Factor Unrelated Inquiry” that follows her analysis of the six Loving factors. See Pet’r’s Posthear’g Br. at 61. Ms. Elson argued that a “Special Master cannot hold that petitioner’s theory is insufficient because the expected outcome was what the petitioner’s current condition looks like.” Oral Arg. Tr. at 600. In Ms. Elson’s view, Sharpe v. Sec’y of Health and Hum. Srvs., 964 F.3d 1072, 1081 (Fed. Cir. 2020), prevents a special master from finding that a vaccinee’s pre-existing problem explains what happened to the vaccinee after the vaccination. *Id.*

While reconciling the Federal Circuit’s statements in Sharpe, Stone, and Doe 11 would be challenging, undertaking that analysis not necessary to resolve Ms. Elson’s claim. Ms. Elson’s case fails primarily because her proof on Loving prong four is not persuasive. The issue addressed under Loving prong four---whether the hepatitis B vaccinations can cause demyelination---is independent of the contribution, if any, of Mr. Hodge’s pre-existing problems. Further, in resolving Loving prong five, the undersigned has generally followed Ms. Elson’s structure of the brief because the analysis largely disregards any evidence of Mr. Hodge’s pre-existing condition.⁹⁷ This method of analysis benefits Ms. Elson because it impairs

⁹⁶ The Secretary is citing Stone v. Sec’y of Health and Hum. Srvs., 676 F.3d 1373, 1380 (Fed. Cir. 2012) (“in some cases a sensible assessment of causation cannot be made ignoring the elephant in the room---the presence of compelling evidence of a different cause for the injury in question”) and Doe 11 v. Sec’y of Health and Hum. Srvs., 601 F.3d 1349, 1358 (Fed. Cir. 2010) (neither the Vaccine Act nor Federal Circuit precedent “limit what evidence the special master may consider in deciding whether a prima facie case has been established”).

⁹⁷ The analysis of Loving prong five contains some minor discussion of the Jarisch-Herxheimer reaction. See Section VI.E above. However, the Jarisch-Herxheimer reaction might explain relatively trivial symptoms that Mr. Hodge experienced between the two hepatitis B vaccinations including any increase in temperature that, according to Ms. Elson, lasted for a few

the Secretary's ability "to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief." Doe 11, 601 F.3d at 1358 (quotation marks and citation omitted).

2. Evidence

Before the vaccinations in March and April 2006, Mr. Hodge suffered from both Lyme disease and OCD. Second Order and Opinion, 164 Fed. Cl. 633, 647 (2023). Further, although the question is not free from all doubt, preponderant evidence shows that Mr. Hodge's Lyme disease caused his OCD. See Section VI.B.2.b. above. Whether this condition or these conditions contribute to Mr. Hodge's health after the vaccinations is explored next.

a) *Lyme Disease*

An infection with the *Borrelia burgdorferi* spirochete progresses through multiple stages when left untreated. See exhibit E-15 at 1100-14 (Wormser) (distinguishing between early Lyme and late Lyme), Exhibit 44 at 447 (Koedel).⁹⁸ The early (or acute) stage of Lyme disease may last weeks. Because the Court found Mr. Hodge developed Lyme disease before September 2004 and because Mr. Hodge received his first hepatitis B vaccination in March 2006, Mr. Hodge's undiagnosed Lyme disease must have reached the late stage. An untreated infection can lead to neurologic symptoms, known as neuroborreliosis. Exhibit 44 at 446 (Koedel), Exhibit 42 at 1082 (Hildenbrand). Dr. Venkatesan agreed that Lyme disease can have neurologic and psychiatric symptoms. Tr. at 388.

To support Dr. Tornatore's contention that a consequence of late Lyme disease can include OCD, Dr. Tornatore testified that Lyme disease is "protean" and a "great imitator." Tr. at 43, 63-64. Both "protean" and "great imitator" are found in a 1995 article. See exhibit E-12 at 297 (Fallon).

days. The Jarisch-Herxheimer reaction cannot explain symptoms that occurred more than a few weeks after the vaccinations.

⁹⁸ Some articles discussed a third stage, sometimes called "post-Lyme disease syndrome." Exhibit E, tab 15 at 1114 (Wormser), Exhibit 44 at 449 (Koedel). This category was intended to group individuals who experienced various problems after being treated for the spirochete. Because Mr. Hodge was not intentionally treated for Lyme disease until 2009, this syndrome does not affect whether the hepatitis B vaccine harmed Mr. Hodge. See Tr. at 102.

Articles corroborate the diversity of manifestations in Lyme disease.⁹⁹ Ways Lyme disease can manifest include meningitis, encephalitis, and myelitis. Exhibit 44 at 448 (Koedel). Another article lists problems in the skin, joints, and heart. Exhibit 40 at 149 (Miklossy). Late neuroborreliosis can produce hallucinations. Id. at 150. Late Lyme disease is also associated with limb paresthesia but rarely. Exhibit E, tab 15 at 1111 (Wormser).

Some articles indicate Lyme disease may produce problems in the eyes. For example, Miklossy lists “affections of . . . eyes,” although the nature of those affections is not otherwise specified. Exhibit 40 at 149 (Miklossy). Hildenbrand details in two paragraphs the typical ocular manifestations of Lyme disease. Exhibit 42 at 1084 (Hildenbrand). Dr. Tornatore stated that neuroborreliosis can affect the “cranial nerves.” Tr. at 43. The third cranial nerve controls the muscles that move the eyes. Dorland’s at 1238 (defining “nervi craniales”), 1294 (defining “oculomotor”). Neuro-Lyme can cause oscillopsia. Tr. at 63-64 (Dr. Tornatore).

Dr. Tornatore expressed the opinion that Mr. Hodge’s disease course without the vaccinations should follow the natural course of Lyme disease. Tr. at 57, see also Tr. at 280. In this context, Dr. Tornatore asserted that people with long-term Lyme disease do not develop new problems acutely. Tr. at 57, see also Exhibit 29 at 8. However, preponderant evidence shows that the development of new symptoms can occur. Dr. Venkatesan provided one example in the form of a very early case report about Lyme disease from Dr. Pachner. Tr. at 427, Exhibit E, tab 11 (Pachner). Dr. Venkatesan also testified he has seen acute problems developed years after the onset of Lyme disease in his Lyme Center. Tr. at 428.¹⁰⁰

The possibility of acute new symptoms in Lyme disease is consistent with the literature. According to Miklossy, untreated Lyme disease (the form Mr. Hodge had before 2009) can progress after years or decades. Exhibit 40 at 150 (Miklossy). Similarly, the Fallon and Nields article indicates neuroborreliosis can develop years after the initial skin infection. Exhibit E, tab 1 (Fallon). When these articles were discussed with Dr. Tornatore, he explained the spirochete can be in a non-eloquent part of the brain, meaning the person will not have symptoms. Tr. at

⁹⁹ Whether the articles support OCD as a manifestation of Lyme disease is questionable. Many articles do not list OCD as a symptom of Lyme disease. See, e.g., Exhibit 44 (Koedel), Exhibit E, tab 15 (Wormser). One article does include OCD but the only authority for the proposition that Lyme disease leads to OCD is the Fallon and Nields article. Exhibit 40 at 150 (reference 80) (Miklossy).

¹⁰⁰ Dr. Tornatore said he has not seen an acute presentation of new problems in his patients with Lyme disease. Tr. at 298-300. However, Dr. Tornatore does not work in a center dedicated to treating patients with Lyme disease.

297. But when the spirochete “hits an eloquent area of the brain, then you will have symptoms.” *Id.* Dr. Venkatesan agreed that the Lyme bacterium can be evasive for years. Tr. at 379. Where the spirochete goes determines what body part is affected. Tr. at 470 (Dr. Tornatore).

In Dr. Venkatesan’s first report, he cited the Pachner, Fallon and Nields, and Fallon articles as reporting that the natural history of Lyme disease can include “progressive or episodic neurologic and/or psychiatric dysfunction.” Exhibit E at 4. Dr. Venkatesan posited that if Mr. Hodge’s “neurologic symptoms” worsened, “the worsening might reflect the clinical course of Lyme neuroborreliosis itself.” *Id.* at 5. Although Dr. Venkatesan could have specified what “symptoms” were part of the clinical course, the previous paragraph of his report talks about dizziness and uncontrollable eye movements.

In Dr. Venkatesan’s testimony, he suggested that it was “possible” the numbness and tingling reported at Encino-Tarzana in August “might have represented neurologic manifestations of Lyme disease . . . that was reported in August 2006.” Tr. at 376. In the oral argument, the Secretary suggested Dr. Venkatesan’s testimony that the June numbness and tingling was from Lyme disease. Oral Arg. Tr. at 531, 576.

Echoing the language Dr. Venkatesan used, the Secretary argues “It is also possible that the symptoms such as fatigue, back pain, and muscle and joint aches that he experienced in the days and weeks following vaccination were the initial manifestations of his Lyme disease.” Resp’t’s Posthear’g Br. at 49. In this respect, Ms. Elson appears to agree, stating “it is likely that [Mr. Hodge’s] unexplained neurological symptoms prior to 2009 were caused by his previously undiagnosed neuroborreliosis.” Pet’r’s Posthear’g Reply at 12, discussing Resp’t’s Posthear’g Br. at 48.

b) OCD

One dimension of Mr. Hodge’s neuroborreliosis was OCD. See Section VI.E. Dr. Tornatore, as previously noted, opined that information about how idiopathic OCD progresses does not inform how Mr. Hodge’s OCD would have progressed but for hepatitis B vaccination. Exhibit 35, Tr. at 57, 280.¹⁰¹ Mr.

¹⁰¹ Ms. Elson obtained this report (Exhibit 35) from Dr. Tornatore when it appeared that petitioners bore the burden of demonstrating their actual course of illness was worse than expected. However, the Federal Circuit has clarified that petitioners do not bear this burden. Sharpe, 964 F.3d at 1081.

Hodge's OCD differed from most cases of OCD because his OCD had a cause – neuroborreliosis.

Factors that contribute to a persistence of OCD include an earlier age of onset. Exhibit E, tab 3 at 1006 (Soomro), Exhibit E, tab 4 at 1 (Eisen), Tr. at 285. The earlier age of onset, in turn, is associated with a higher frequency of OCD in first-degree relatives. Exhibit E, tab 4 at 7 (Eisen), ¹⁰² see also Exhibit E, tab 3 at 1006 (Soomro), Tr. 367-68 (Dr. Venkatesan's testimony about Mr. Hodge's family history of OCD), Tr. at 282 (Dr. Tornatore acknowledging a strong familial component to OCD); but see Tr. at 49 (Dr. Tornatore's assertion that a family history is not relevant for Mr. Hodge).

The experts agree that a natural course of (at least idiopathic) OCD waxes and wanes. Exhibit E at 4, Exhibit 35 at 1.¹⁰³ Sometimes, the overall course of OCD progresses or worsens. Id., see also Exhibit E, tab 3 at 1005 (Soomro), Exhibit E, tab 4 at 2 (Eisen) (indicating that before treatments were discovered, this illness was usually chronic and lifelong).

Although Dr. Tornatore indicated natural idiopathic OCD can wax and wane, he opined he did not expect a person with OCD to develop new problems acutely. Exhibit 35, Tr. at 283. In Dr. Tornatore's view, the person's brain "changes glacially" unless something like an external trigger perturbed it. Tr. at 284. To Dr. Tornatore, "What is striking in Mr. Hodge's case was the dramatic change in his symptoms immediately following the hepatitis vaccinations." Exhibit 35 at 1. Ms. Elson repeats this point. Pet'r's Posthear'g Br. at 46.

Dr. Venkatesan sees OCD differently. In his view, the progression of OCD can include not only a worsening of symptoms but also the development of new problems. Tr. at 404-10.

On these points, Dr. Tornatore is partially persuasive and partially unpersuasive. Dr. Tornatore is persuasive in questioning the assertion that people with long-term OCD develop new problems. Dr. Venkatesan was not persuasive in asserting the people with long-term OCD develop new problems. The few articles about OCD in the record discussed the persistence of OCD and difficulty of treating OCD. However, a continuation of problems differs from the addition of new problems. (In this way, OCD seems different from Lyme disease in which

¹⁰² The Secretary submitted the Eisen article in manuscript form. Therefore, published page numbers are not available.

¹⁰³ Neither expert seemed especially strong in OCD.

articles indicate people can start having new problems years after the initial infection.)

On the other hand, any suggestions that Mr. Hodge's OCD abruptly changed after the vaccination is problematic. This comparison has problems in both the before and after pictures.

Before the vaccination, reliable information about Mr. Hodge's OCD is limited. Mr. Hodge stopped going to school and his OCD contributed to withdrawing from school. See Exhibit 14 at 451 (Dr. Dasher's October 22, 2009 record indicating that Mr. Hodge had to drop out of school due to confusion); Tr. at 146.¹⁰⁴ The Court has found Mr. Hodge's OCD was manifest no later than September 28, 2004. On March 21, 2005, Mr. Hodge was taking medications that can treat OCD. Exhibit 3.1 at 4; Tr. at 303. About one year later, Dr. Rodriguez's March 2006 history indicates that Mr. Hodge has OCD. Exhibit 5 at 2. Mr. Hodge was taking a medication for OCD. Id. at 6. He was treated with an unnamed psychologist or psychiatrist. At the hearing, Ms. Elson maintained that before the vaccination, Mr. Hodge spent time checking lights, faucets, the oven. Tr. at 146-47.

Before the vaccinations, Mr. Hodge was treated for mental health issues by people in two locations: West Valley and in the office of Dr. Nasse. Ms. Elson did not provide records from these sources and Dr. Tornatore expressed an interest in seeing them. Tr. at 305-06.¹⁰⁵

Ms. Elson's characterizes Mr. Hodge's OCD as "mild." Pet'r's Posthear'g Br. at 17, 30, 39, but the support for this characterization is minimal. When asked during oral argument about whether Mr. Hodge's OCD was mild, Ms. Elson's attorney stated "we don't know either way because... There's no records." Id. at 518. The attorney added "There's no evidence in the record that's available that his OCD was significant enough to massively interfere with his life." Id. Counsel's recognition that we don't know the extent of Mr. Hodge's OCD is consistent with the view of Dr. Tornatore. When asked about the details of Mr. Hodge's OCD when he came to Dr. Rodriguez's office, Dr. Tornatore said "I don't

¹⁰⁴ Although Ms. Elson wrote that Mr. Hodge's OCD did not interfere with his daily life (Exhibit 71 at 2), she also stated that "ordinary high school overwhelmed him." Exhibit 21 at 1.

¹⁰⁵ Dr. Tornatore could accurately state that before the vaccination, no evidence showed that Mr. Hodge had abnormal eye movements. However, Mr. Hodge could have reported abnormal eye movements to Dr. Nasse. See Tr. at 306-08.

know... There is no documentation as to what the phenomenology of that was.” Tr. at 302.

Despite not knowing how Mr. Hodge’s OCD was before the vaccinations, Dr. Tornatore characterized Mr. Hodge’s change as “striking.” Exhibit 35 at 1. Dr. Tornatore measured this change in visits to the emergency room. Id.

However, after the vaccinations, in the visits to the emergency room at Valley Presbyterian in June 2006 and Encino-Tarzana in August 2006, there were no complaints about a worsening of OCD symptoms. OCD was merely documented. See Exhibit 6 at 7 and Exhibit 4 at 4. The Encino-Tarzana record is especially significant in that it affirmatively notes that Mr. Hodge has OCD but does not say his OCD is worse. Ms. Elson also averred that Mr. Hodge’s OCD was about the same in the summer 2006. Exhibit 86 at 18-20. Further, Ms. Elson’s attorney placed the worsening of OCD in November 2007. Oral Arg. Tr. at 579. Taken together, this information preponderantly establishes that Mr. Hodge’s OCD did not worsen within six months of his vaccinations.

To be sure, Dr. Tornatore did not precisely say that the “striking” contrast was in his OCD symptoms. Instead, Dr. Tornatore stated that Mr. Hodge had new neurologic symptoms. Exhibit 35 at 1. As discussed extensively above, problems like abnormal eye movements and paresthesias could be neurologic in origin, perhaps due to neuroborreliosis. See section VI.E. above. Regardless of whether these isolated and temporary problems were neurologic, Dr. Tornatore has not persuasively connected the eye problems or body problems to Mr. Hodge’s OCD. But see Tr. at 375 (Dr. Venkatesan stating OCD can produce somatic complaints).

Eventually and unfortunately, Mr. Hodge’s OCD did worsen. Various mental problems were reported on July 10, 2007, at West Valley Mental Health Center. Exhibit 11 at 3-12. Although there was no follow-up treatment at West Valley, Mr. Hodge started intense treatment at Transitional Youth in November 2007. Exhibit 10, passim. More than three years after the vaccinations, Dr. Munoz was informed that Mr. Hodge had an “abrupt onset [of] OCD-like behavior... That has since waxed and wane with periods of normalcy.” Exhibit 7.1 at 46 (Aug. 4, 2009).

To the extent that the history given to Dr. Munoz is accurate, the “waxing and waning” sequence matches Dr. Venkatesan’s and Dr. Tornatore’s description of natural idiopathic OCD. See exhibit E at 4, Exhibit 35 at 1. This evidence further undermines Ms. Elson’s proof that the vaccination was the reason for the worsening of Mr. Hodge’s OCD.

3. Assessment

The Secretary is not asserting that some factor (such as pre-existing Lyme disease) caused Mr. Hodge's condition after the vaccination. See Resp't's Posthear'g Br. at 66-67, Oral Arg. Tr. at 521-23, 549-51. Thus, if Ms. Elson had presented preponderant evidence under all six Loving prongs, then the Secretary could not be found to have met any affirmative burden of proof. The Secretary has effectively disclaimed any argument that preponderant evidence shows that either Lyme disease, OCD, or Lyme disease and OCD explain Mr. Hodge's health. See Vaccine Rule 8(f).

On the other hand, to the extent that the Federal Circuit authorizes a special master to consider factors unrelated to the vaccinations as evidence undermining a petitioner's attempt to establish a prima facie case, then the evidence regarding Mr. Hodge's health before the vaccination presents another obstacle. It is plausible that Mr. Hodge's mental and physical condition after the vaccination reflects how an untreated case of an infection with the *Borrelia burgdorferi* spirochete progresses. However, this point is academic in that the outcome of Ms. Elson's case depends on her inability to establish with persuasive evidence all of the Loving prongs, especially prong four. In other words, the same result would have been reached without this section VI.G.

VII. Conclusion

Ms. Elson has demonstrated her love and care for son. Mr. Hodge is suffering from difficult diseases in difficult situations, and, by extension, Ms. Elson suffers with her child. She additionally expressed guilt for bringing him for vaccinations that were intended to protect him, but, in her mind, harmed him. Tr. at 233. For these circumstances, Ms. Elson and Mr. Hodge warrant sympathy.

Nevertheless, the requirements of the Vaccine Act must be satisfied before compensation can be awarded. Here, Ms. Elson has not carried her burden of demonstrating that the hepatitis B vaccine can aggravate (or cause) demyelination. Thus, her claim for compensation is DENIED.

The Clerk's Office is directed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including any deadlines, can be found in the Vaccine Rules, which are available on the web site for the Court of Federal Claims. The Clerk's Office is further directed to provide this decision to the assigned judge pursuant to Vaccine Rule 28.1(a).

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master

Appendix

1. Jan C. Beucke et al., Default mode network subsystem alterations in obsessive-compulsive disorder, 205 THE BRIT. J. OF PSYCHIATRY 376 (2014); filed as Exhibit E-8.
2. Dimitrios-Petrou Bogdanos et al., A study of molecular mimicry and immunological cross-reactivity between hepatitis B surface antigen and myelin mimics, 12 CLINICAL & DEVELOPMENTAL IMMUNOLOGY 217 (2005); filed as Exhibit 48.
3. Yannick Comenge & Marc Girard, Multiple sclerosis and hepatitis B vaccination: Adding the credibility of molecular biology to an unusual level of clinical and epidemiological evidence, 66 MED. HYPOTHESES 84 (2006); filed as Exhibit 50.
4. Jane L. Eisen et al., A 2-Year Prospective Follow-Up Study of the Course of Obsessive-Compulsive Disorder, 71 J. CLINICAL PSYCHIATRY 1033 (2010); filed as Exhibit E-4.
5. Brian A. Fallon & Jenifer A. Nields, Lyme Disease: A Neuropsychiatric Illness, 151 AM. J. PSYCHIATRY 1571 (1994); filed as Exhibit E-1.
6. Brian A. Fallon et al., Late-Stage Neuropsychiatric Lyme Borreliosis: Differential Diagnosis and Treatment, 36 PSYCHOSOMATICS 295 (1995); filed as Exhibit E-12.
7. Mohsen Foroughipour et al., Frequency of obsessive-compulsive disorder in patients with multiple sclerosis: A cross-sectional study, 17 J. RES. IN MED. SCI. 248 (2012); filed as Exhibit 39.
8. Jennifer Graves and Laura J. Balcer, Eye disorders in patients with multiple sclerosis: natural history and management, 4 CLINICAL OPHTHALMOLOGY 1409 (2010); filed as Exhibit 54.
9. P. Hildenbrand et al., Lyme Neuroborreliosis: Manifestations of a Rapidly Emerging Zoonosis, 30 AM. J. NEURORADIOLOGY 1079 (2009); filed as Exhibit 42.
10. Pooja Kadam et al., Delayed Onset of the Jarisch-Herxheimer Reaction in Doxycycline-Treated Disease: A Case Report and Review of its Histopathology and Implications for Pathogenesis, 37 AM. J. DERMATOPATHOLOGY 68 (2015); filed as Exhibit E-14.
11. Kathrin Koch et al., Diffusion tensor imaging (DTI) studies in patients with obsessive-compulsive disorder (OCD): A review, 54 J. PSYCHIATRIC RES. 26 (2014); filed as Exhibit E-6.

12. Uwe Koedel et al., Lyme neuroborreliosis—epidemiology, diagnosis and management, 11 NATURE REV. NEUROLOGY 446 (2015); filed as Exhibit 44.

13. Fei Li et al., Microstructural Brain Abnormalities in Patients with Obsessive-Compulsive Disorder: Diffusion-Tensor MR Imaging Study at 3.0 T, 260 RADIOLOGY 216 (2011); filed as Exhibit 46.

14. Makoto Matsui et al., Recurrent demyelinating transverse myelitis in a high titer HBs-antigen carrier, 139 J. NEUROLOGICAL SCIENCES 235 (1996); filed as Exhibit 51.

15. Judith Miklossy, Chronic or Late Lyme Neuroborreliosis: Analysis of Evidence Compared to Chronic or Late Neurosyphilis, 6 THE OPEN NEUROLOGY J. 146 (2012); filed as Exhibit 40.

16. Mohammad R. Milad & Scott L. Rauch, Obsessive Compulsive Disorder: Beyond Segregated Cortico-striatal Pathways, 16 TRENDS IN COGNITIVE SCI. 43 (2011); filed as Exhibit E-7.

17. M.B.A. Oldstone, Molecular Mimicry, Microbial Infection, and Autoimmune Disease: Evolution of the Concept, 296 CURRENT TOPICS IN MICROBIOLOGY AND IMMUNOLOGY 1 (2005); filed as Exhibit 47.

18. Andrew Pachner et al., Central Nervous System Manifestations of Lyme Disease, 46 ARCHIVES OF NEUROLOGY 790 (1989); filed as Exhibit E-11.

19. Greta Ramesh et al., Inflammation in the Pathogenesis of Lyme Neuroborreliosis, 185 THE AM. J. PATHOLOGY 1344 (2015); filed as Exhibit 43.

20. Yukiko Saito et al., Corpus Callosum in Patients with Obsessive-Compulsive Disorder: Diffusion-Tensor Imaging Study, 246 RADIOLOGY 536 (2008); filed as Exhibit 45.

21. Lawrence B. Schonberger et al., Guillain-Barre Syndrome Following Vaccination In The National Influenza Immunization Program, United States, 1976-1977, 110 AM. J. EPIDEMIOLOGY 105 (1979); filed as Exhibit 52.

22. Signs and Symptoms Consistent with Demyelinating Disease, NAT'L MULTIPLE SCLEROSIS SOCIETY, <https://www.nationalmssociety.org/For-Professionals/Clinical-Care/Diagnosing-MS/Signs-and-Symptoms-Consistent-with-Demyelinating-D> (last visited Jun. 26, 2018); filed as Exhibit 55.

23. G. Mustafa Soomro, Obsessive compulsive disorder, 2012 BMJ CLINICAL EVIDENCE 1004 (2012); filed as Exhibit E-3.

24. Silvia Tenembaum et al., Acute disseminated encephalomyelitis: A long-term follow-up study of 84 pediatric patients, 59 NEUROLOGY 1224 (2002); filed as Exhibit 53.
25. Burton A. Waisbren Sr., Acquired Autoimmunity After Viral Vaccination Is Caused By Molecular Mimicry And Antigen Complimentarity In The Presence Of An Immunologic Adjuvant And Specific HLA Patterns, 70 MED. HYPOTHESES 346 (2008); filed as Exhibit 49.
26. Gary P. Wormser et al., The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America, 45 CLINICAL INFECTIOUS DISEASES 941 (2007); filed as Exhibit E-15.